

NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY

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PURGE PROCEDURES AND LEAK TESTING FOR THE MORGAN BREATHING SYSTEM (MBS) 2000 CLOSED-CIRCUIT OXYGEN REBREATHING:

by

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**PURGE PROCEDURES AND LEAK TESTING FOR THE
MORGAN BREATHING SYSTEM (MBS) 2000 CLOSED-CIRCUIT
OXYGEN REBREATH**

Report prepared for
NAVSEA 00C

Report prepared by
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Executive Summary

INTRODUCTION

The MBS 2000 is a closed-circuit oxygen rebreather designed to provide oxygen for on-scene decompression of submarine survivors and recompression treatment of divers aboard submarines. There are concerns in each of these applications about having enough oxygen to support remote operations and having sufficient ventilation capacity to prevent excess O₂ leaking into the compartment. For the Deep Submergence Rescue Vehicle, which cannot be ventilated, the concern is the rate at which the mid- and aft-sphere O₂ concentrations will rise. Since purging accounts for most of the O₂ used when breathing on the MBS 2000, optimizing the purge procedure will maximize the duration of the O₂ supply and minimize oxygen leaks into the chamber atmosphere. Therefore the overall goal of the present study was to develop efficient purge procedures and determine leak rates for the current version of the MBS 2000. This was accomplished via three experiments. The first experiment focused on identifying the optimum purge procedure. The second experiment used the optimum purge procedure from Experiment 1 to determine mask leak rates and the build up of O₂ in the chamber in clean-shaven and unshaven subjects. The final experiment evaluated two design modifications to the MBS 2000 and the effectiveness of these modifications for reducing the purge volume. The specific objectives for the three phases are given below.

OBJECTIVES

1. Determine the simplest and most efficient way to purge the MBS 2000.
2. Determine the relationship between the inspired oxygen fraction achieved and the volume of O₂ used for a purge.
3. Assess differences in purge efficiency between divers and submariners.
4. Obtain O₂ consumption and rig leakage data that will allow calculation of the total volume of O₂ needed to support an operation.
5. Determine the average number of purges required to maintain the O₂ level in the breathing loop above 75%, above 80%, above 85% and above 90% during a 60 min breathing period following an initial purge.
6. Determine mask leak rates in shaven and unshaven subjects at 1 ATA.
7. Determine the rate of build up of O₂ in the enclosed atmosphere of the chamber over a 60 min period.
8. Compare the effectiveness of a single 15 sec purge procedure with a 2 x 15 sec purge (CR15 purge procedure) to determine if reducing the purge volume by approximately one half would significantly impact the starting FiO₂ and the rate of decline in FiO₂ during closed-circuit breathing following an initial purge.
9. Determine the effectiveness of two MBS 2000 design modifications (a pop-off valve and a Y-valve) on purge efficiency.

METHODS

All experiments were conducted at 1 ATA. For Experiments 1 and 2 subjects were 9 submariners, age 21.6±6.9 (mean±SD) yrs, 4.8±0.6 L vital capacity (VC) and 9 divers, age 34.0±11.8 yrs, 5.3±0.6 L VC. A subset of these subjects (7 divers and 1 submariner) participated as subjects in Experiment 3. Throughout each experiment the FiO₂ of each unit was monitored using an O₂ cell placed on the inspired side of the rebreathing circuit. The volume of oxygen

used by each subject was monitored by measuring changes in bottle pressure. In Experiment 1 each subject conducted five different purge procedures. Purge efficiency for each purge procedure was determined by comparing the volume of O₂ used for the purge with the point sample FiO₂ achieved after 30 s of rebreathing. Differences in purge volume and FiO₂ achieved between the five purge procedures were assessed using a split plot repeated measures ANOVA design.

Experiment 2 was performed with subjects seated at rest in the 307 cubic foot inner lock of NSMRL's treatment chamber. Trials consisted of a single 60-min O₂-breathing period in which subject's purged the MBS-2000 at the start of the test and then again only if their FiO₂ dropped below 0.70. Each subject completed a clean-shaven trial (CT) followed by an unshaven trial (UT) after abstaining from shaving for 7-14 days. The purge procedure used during Experiment 2 involved two 15 sec purges in which the subject depressed the regulator purge button and conducted 3 VC breaths during each 15 sec purge. During each trial the rate of rise of the O₂ concentration in the chamber atmosphere was monitored using a paramagnetic O₂ analyzer. Estimates of the volume of O₂ dumped into the chamber was calculated at 15 min intervals by subtracting metabolic O₂ consumption and the combined O₂ volume remaining in the supply lines, lungs and rebreathing circuit from the total volume of O₂ used. Differences in O₂ usage and O₂ volume dumped into the chamber between trials for different levels of beard growth (light, medium, and heavy) were analyzed using repeated measures ANOVA.

The procedure for Experiment 3 was the same as that for Experiment 1. Each subject performed four different reduced-volume purge procedures using modified MBS 2000 rigs. The reduced volume purge procedures were designed to use approximately half the volume of O₂ than that used for the CR15. Two of the purge procedures used the MBS 2000 fitted with a newly designed pop-off valve. In the other two purges a Y-valve was incorporated in the exhaled breathing line to assist with purging. The efficiency of the reduced volume purges with the modified MBS 2000 was compared with the CR15 purge and the unmodified MBS 2000 using repeated measures ANOVA.

RESULTS

Results of Experiment 1 showed that the best compromise between purge volume, starting FiO₂ and simplicity of operation was the CR15 purge. This purge procedure involves two 15 sec purges in which the subject performs 3 VC breaths during each 15 sec while depressing the regulator purge button. Thirty seconds of rebreathing separated the two 15 sec purges to allow for gas mixing in the lungs and rebreathing circuit. The CR15 was able to raise the mean FiO₂ above 0.90 using two thirds less volume than that used by the currently recommended (CR) purge procedure (i.e. 28 vs. 81 liters). Over the five different purge procedures, divers used significantly more O₂ than the submariners but achieved an FiO₂ level that was on average 0.09 above the submariners. Using data from single vital capacity purges, the relationship between the FiO₂ achieved and the VO₂ used was found to be an exponential function that predicted at least 6 VC were required to raise the FiO₂ within the breathing circuit from 0.21 to >0.90.

Results from Experiment 2 showed a significant two-way interaction between beard growth category and the difference in the number of purges between CT and UT ($p < 0.05$). Post hoc analysis revealed that subjects with light and medium beard growth showed no change in the

number of purges between the CT and UT, whereas subjects with heavy beard growth significantly increased the number of purges during the UT ($p < 0.05$). Oxygen usage during UT for these latter subjects was more than double that during their CT ($p < 0.05$). The amount of O_2 leaking into the chamber increased significantly over time ($p < 0.0001$) and was greater during the unshaven trials compared to the shaven trials (Mean \pm SD leak rate for shaved trials = 0.94 ± 0.64 l/min/man, unshaved = 1.50 ± 1.19 l/min/man, $p < 0.05$). For CT it appears that after the initial high leak rate at 15 minutes, leak rates remain constant at approximately 0.8 l/min for the remainder of the trial. In contrast, oxygen leak rates appear to fall over time during UT.

Results of Experiment 3 showed that the reduced volume purge procedures using the pop-off valve configuration were unable to raise the initial FiO_2 to >0.90 . In contrast a single 15 sec purge performed using the Y-valve modification achieved the same starting FiO_2 as for the unmodified MBS 2000 using the CR15 purge (i.e. both $FiO_2 = 0.93$), but with half the volume. However, post hoc analysis of the significant two-way interaction between purge procedure and time interval ($p < 0.005$) revealed that the rate of decrease in FiO_2 was greater following the single 15 sec purge with the Y-valve modification than that following the CR15 purge.

CONCLUSIONS

- Divers use more O_2 than submariners during the purge procedures but attain a higher FiO_2 than the submariners.
- The simplest and most preferred purge procedure is the CR15.
- The CR and CR15 purge procedures were the only procedures tested that achieved a starting $FiO_2 > 0.90$.
- The CR and CR15 purge procedures achieve a similar FiO_2 , but the CR15 purge achieves this using approximately two thirds less O_2 than the CR purge.
- A mathematical model of the change in FiO_2 following each VC purge predicts that at least 6 VC purges are required to raise the FiO_2 in the MBS 2000 from 0.21 to > 0.90 .
- Heavy beard growth increases the amount of chamber air leaking around the sides of the MBS 2000 oral nasal mask into the breathing circuit, leading to an increased purge frequency and an increase in the volume of O_2 used to maintain the FiO_2 above a given level. This increased purge frequency can more than double the O_2 requirements needed for a treatment.
- During the first 15-minute O_2 period the high rate of O_2 leaking into the chamber atmosphere reflects the volume of O_2 used during the initial purge. After the initial 15-min period the average rate of O_2 leaking into the chamber atmosphere/man in clean-shaven subjects is approximately constant at 0.8 l/min. This leak rate assumes that subsequent purges are performed only when the FiO_2 in the rebreathing circuit drops below 0.70.
- A single 15-second purge using the pop-off valve configuration was unable to raise the FiO_2 in the breathing circuit above 0.90.
- An initial $FiO_2 > 0.90$ can be achieved with a purge volume of approximately 15 liters in well trained subjects using the Y-valve configuration, but that more than 15 liters of O_2 are required if FiO_2 levels within the MBS 2000 breathing loop are to be maintained above 0.80 for longer than 5 minutes.

Introduction

In 2000 the Naval Submarine Medical Research Laboratory (NSMRL) was tasked by Naval Sea Systems Command (NAVSEA) to evaluate commercial closed-circuit oxygen rebreather systems to be used to provide hyperbaric oxygen treatment to support a large scale, mobile decompression treatment program for submarine escape and rescue situations. Unmanned testing was performed on 5 prototype closed circuit rebreather systems that were narrowed down to two prototypes for final human testing. The two units that underwent human testing were the Diving Systems International (DSI) and the US Divers (USD) units. Since both of the final prototype units performed similarly in their task of delivering oxygen to the patient, the final recommendation to NAVSEA was that the DSI and the USD units be considered for Navy use. The test plan and results of this tasking are described in detail in NSMRL Technical Report 1215 (White et al., 2000).

Since conducting the original acceptance testing of the DSI prototype oxygen rebreather, several hardware modifications have been made, a new purge procedure has been adopted and the unit renamed the Morgan Breathing System (MBS) 2000. The MBS 2000 has been used operationally to provide oxygen during experimental chamber dives at the Naval Experimental Diving Unit (NEDU). During the NEDU trials it was found that the volume of oxygen consumed by the MBS 2000 was substantially higher than that measured for the DSI unit during acceptance testing. The reason for the discrepancy is not clear. However, the presently adopted purge procedure is a major source of oxygen usage and is currently not optimized to minimize gas usage.

The Navy intends to use the MBS 2000 to supply oxygen for decompression of submarine survivors in the Submarine Rescue Chamber (SRC), Deep Submergence Rescue Vehicle (DSRV), and Submarine Rescue Diving and Recompression System (SRDRS) and for recompression treatment of divers in the VA class SSN lock out trunk and the SSGN lock out chamber. There are concerns in each of these applications about having enough oxygen to support the operation and having sufficient ventilation capacity to remove excess oxygen leaking into the compartment. For the DSRV, which cannot be ventilated, the concern is the rate at which the mid- and aft-sphere oxygen concentrations will rise.

Since purging accounts for most of the oxygen consumed by the MBS 2000, it is therefore the largest contributor to a rise in compartment oxygen levels and ventilation requirement. One of the objectives of the current study is therefore to develop a more efficient purge procedure that will minimize O₂ usage while attaining the desired inspired oxygen level. Minimizing the amount of oxygen needed to purge the MBS 2000 will reduce the total amount of oxygen required in support of the above applications as well as reduce the rate of build up in compartment oxygen levels.

A second concern for the MBS 2000 was that the hardware modifications to the original DSI unit could have potentially introduced new areas where leaks could occur. Leaks resulting in either air (nitrogen) leaking/diffusing into the closed circuit or oxygen leaking out of the circuit will both result in increased oxygen usage due to increased purge frequency needed to maintain a given FiO₂. Of more concern is that leaks of air into the closed circuit will reduce the

oxygen dosage to the patient, which if severe, could potentially reduce the effectiveness of the decompression treatment.

Since the MBS 2000 uses an oral nasal mask to deliver oxygen to the patient, factors that affect mask fit such as mask design, face anthropometrics and facial hair will likely influence the amount of air leaking into the closed-circuit breathing loop. Given that it may take several days to affect a rescue of DISSUB survivors, it is likely that many submariners at the time of rescue will have a significant amount of facial hair. Thus a second objective of the current study was to compare leak rates with the MBS 2000 in clean-shaven and unshaven subjects.

The current report has been divided into several sections that deal with the purge procedures and leak test issues described above. The first section outlines the experiments performed to determine the best purge procedure for the MBS 2000. In the second section the optimum purge procedure is used during leak test trials at 1 ATA in clean-shaven and unshaven subjects. The final section evaluates purge procedures in a modified version of the MBS 2000. The hardware modifications made to the MBS 2000 resulted from the findings of the first two studies and were a pilot attempt to improve the efficiency and safety of the purge procedures. The individual experiments are presented in chronological order with the specific objectives for each study given at the start of each section.

1. Purge Procedures

Objectives

- I. At 1 ATA, determine the volume of oxygen consumed and the inspired oxygen fraction achieved using the current recommended purge procedures.
- II. At 1 ATA, determine the simplest and most efficient way to purge the MBS 2000.
- III. Determine the relationship between the inspired oxygen fraction achieved and the volume of oxygen used for a purge.

Methods

Subjects

Subjects were 9 submariners (mean \pm SD age = 21.7 ± 6.9 yrs, forced vital capacity (FVC) = 4.9 ± 0.6 L BTPS) and 9 divers (age = 34.7 ± 11.8 yrs, FVC 5.4 ± 0.6 L BTPS). Most of the submariners were recruited from the Basic Enlisted Submarine School at the Submarine Base, New London and were significantly younger than the diver group ($p < 0.05$). The diver group consisted of US Navy trained divers from NSMRL and the Escape Trainer at the Submarine Base New London. Despite differences in the mean age of the two groups there was no significant difference in the mean FVC between the diver and submariner group. Subjects were briefed on the studies objective and provided informed consent.

Apparatus

A total of six MBS 2000 units were received from Ocean Engineering for the tests. In addition, three pairs of new yellow vinyl breathing bags and three new cast main bodies incorporating a toggle overpressure relief valve were received from Dive Labs, Inc. The new breathing bags and cast main bodies were assembled with the regulators and breathing hoses/mouthpieces from Ocean Engineering to make a total of 3 MBS 2000 units, which were used throughout all the subsequent tests. Each subject was provided with a leak-tested (see below) MBS 2000 closed-circuit oxygen rebreather fitted with a CO₂ absorbent canister filled with 812 NI D grade Sofnolime™ (see Fig 1). The dead space volume for the MBS 2000 was calculated to be approximately 1.34 l with the breathing bags fully evacuated and with the CO₂ canister filled with approximately 1.1 kg of 812 grade Sofnolime™. Individual oxygen cylinders (255 l capacity M9 oxygen cylinders) supplied 100% medical grade oxygen to each MBS 2000 unit. Each oxygen cylinder was instrumented with a DP15-64 pressure transducer (Validyne Engineering, Northridge, CA) to monitor changes in bottle pressure. Output from the DP15-64 pressure transducers were amplified using CD 18 carrier demodulators before being sampled by the analogue to digital (A/D) recording system. The volume of oxygen used (in liters at 1 ATA and 25 °C) over a given time period was calculated from the changes in bottle pressure. The second stage over bottom pressure for the regulator was set at 70 psi for all tests.

Oxygen levels within the MBS 2000 closed circuit were monitored continuously using a T-7 oxygen sensor (Teledyne Analytical Instruments, Industry, CA) inserted into the inspired side of the main body assembly using a custom designed coupling (see Fig. 1b). Output from the O₂ sensor was amplified using a Gould DC amplifier before being passed to the A/D recording system.

Pre-test leak testing

Each of three MBS 2000 units were leak tested by injecting oxygen into the breathing circuit and then sealing the mouthpiece by pushing in the T-assembly plunger. With the oxygen pressurizing the closed circuit breathing loop, dousing potential leak areas with soapy water and watching for bubbles provided a way to detect any leaks. Leaks that were detected were sealed or minimized before operating the unit. Each unit was also internally pressurized by forcing air into the closed-circuit loop using a 3 liter calibrated syringe to determine the magnitude pressure increase that would occur within the closed-circuit loop as a function of the volume of gas added. During this latter procedure the pressure within the breathing loop was measured using a Validyne pressure transducer (Model DP9-32, Validyne Engineering, Northridge, CA) mounted in the gas sample port of the main valve body (see Fig 1).

Purge Procedures

Before conducting the purge procedures listed below each subject's vital capacity (FVC) was measured using a S430A Ventilation Measuring System (K.L Engineering, Northridge, CA). The FVC used in analysis was the best of three efforts. Subjects were then shown how the rig operated and were given verbal instructions on each purge procedure prior to conducting the purges. They did not practice the purge procedures and only performed each purge procedure once except when technical difficulties dictated a repeat purge be performed. During the performance of each purge procedure the subject was given verbal step-by-step instructions by the experimenter.



Figure 1: (a) The MBS 2000 closed-circuit oxygen rebreather (left). (b) A close up picture of the main body and CO₂ absorbent canister showing the custom built insert used to mount the T-7 O₂ sensor in the inspired side (green dot) of the breathing circuit (bottom). During most experimental trials the pressure transducer shown connected to the main body was replaced with a quick connect gas sample port.



Before each purge procedure the MBS 2000 unit was flushed with room air using a hair dryer set on the cool setting until the oxygen content in the rig was the same as that of room air. Subjects then evacuated the breathing bags by inhaling on the rig without the oxygen whip connected to the O₂ supply. Once the breathing bags were fully evacuated the slider/plunger valve on the mouthpiece was closed. Subjects then performed each of the purge procedures described below in a random order. An air break of approximately 5 minutes separated consecutive purge procedures.

- Current recommended Purge Procedure (CR)

The current recommended purge procedure involved the following processes. After fully exhaling to residual volume the subject dons the MBS 2000 mask and conducts a 30 sec purge by breathing deeply on the breathing system while simultaneously pressing the MBS 2000 overpressure relief toggle and regulator purge valves. After the 30 sec purge the subject releases the regulator cover and over pressure relief valve and breathes normally for 30 sec. The above procedure is repeated two more times before commencing normal breathing on the unit.

- Modified purge procedure 1: single fill/empty cycle (SFE)

For a single fill empty cycle the subject ensures the MBS breathing bags are fully deflated. He then closes the slider/plunger valve on the mouthpiece manifold and fills the breathing bags to full capacity by depressing the regulator purge valve. The subject then exhales to RV and dons the MBS mask, opens the slider/plunger and takes a big deep breath in. He then closes the plunger valve and exhales to atmosphere. The subject repeats the above procedure of inspiring from the breathing bags and exhaling to atmosphere until the breathing bags are fully deflated. The exhaled breath immediately following the inhaled breath that fully collapses the breathing bag is directed through the closed circuit while simultaneously squeezing the breathing bags and pressing the pressure relief valve to purge the expired side of the breathing circuit. After the end of this exhalation the subject releases the pressure relief valve and takes a deep inspiration to provide sufficient volume for comfortable breathing. The subject then breathes normally on the rig.

- Modified purge procedure 2: single-breath vital capacity maneuver (VC1)

The single-breath vital capacity purge maneuver (1VC) involves the subject completely evacuating the MBS 2000 breathing bags by squeezing the air out of them. He then exhales to residual volume (RV) and dons the MBS 2000 mask. With the breathing bags remaining fully compressed he inspires to total lung capacity, then closes the slider/plunger valve on the mouthpiece and exhales to RV allowing the exhaled breath to escape around the sides of the oral nasal mask. During the exhalation he rolls up the breathing bags. At the end of exhalation he opens up the slider/plunger valve on the mouthpiece using one hand and then toggles the overpressure relief valve and fully exhales to RV while simultaneously squeezing the breathing bags to purge the expired side of the breathing circuit. At the end of exhalation he releases the overpressure relief valve and breathing bags and takes a deep inspiration to provide sufficient volume for comfortable breathing. He then continues to breathe normally on the MBS 2000.

- Modified purge procedure 3: Multiple-breath vital capacity maneuver (MVC)

The MVC purge procedure is performed in a similar manner as the VC1 maneuver. After completely evacuating the MBS 2000 breathing bags by squeezing the air out of them the subject exhales to residual volume (RV) and dons the MBS 2000 mask. With the breathing bags remaining fully compressed the subject inspires to total lung capacity, then closes the slider/plunger valve on the mouthpiece and exhales to RV allowing the exhaled breath to escape around the sides of the oral nasal mask. At the end of exhalation the subject opens the slider/plunger valve on the mouthpiece and takes a deep inspiration to provide sufficient volume for comfortable closed-circuit breathing. The subject breathes normally on the closed circuit for 30 sec. If after 30 sec the inspired fraction of oxygen is less than 90% the above procedure is repeated. The above vital capacity maneuver was repeated every 30 sec until either (1) the inspired fraction of oxygen within the closed circuit at the end of a 30 sec rebreathing period was $\geq 90\%$ or (2) there was no change in the FiO_2 between successive VC cycles or, (3) 6 min of data had been collected.

- Modified purge procedure 4: Reduced volume version of the current recommended purge procedure (CR15)

During pilot tests on a couple of subjects it became clear that the CR purge procedure may be made more efficient by reducing both the duration and number of purges without markedly reducing the final FiO_2 . The CR purge procedure was therefore adapted in an attempt to reduce the amount of O_2 used by approximately two thirds by adopting the procedures below. After fully exhaling to residual volume, the subject dons the MBS 2000 mask and conducts a 15 sec purge by pressing the MBS 2000 regulator purge valve. During the 15 sec purge the subject conducts 3 deep breaths allowing the exhaled portion of the breath to escape around the sides of the oral nasal mask. After the 15 sec purge the subject releases the regulator cover and breathes normally for 30 s. The above 15 sec purge procedure is repeated one more time before commencing normal breathing on the unit.

Data collection and analysis

Prior to each purge procedure the mass and pressure of the oxygen cylinder (M9) was recorded. The bottle mass was determined to the nearest 0.1 g using a calibrated Sartorius Combics 9 kg capacity mass scale (Sartorius AG, Goettingen, Germany). Each purge test was conducted for 6 minutes with bottle pressure and FiO_2 measured and recorded on line at a sampling frequency of 50 Hz using a BIOPAC MP100 A/D system (BIOPAC Systems, Inc, Santa Barbara, CA) interfaced with a laptop computer. At the end of 6 min of data collection the oxygen bottle was reweighed to determine the total mass of oxygen used over the 6 min period. The inspired fraction of oxygen achieved after each purge maneuver was derived from the instantaneous value for FiO_2 recorded 30 s after commencing normal closed circuit breathing. This was done to allow complete mixing of the oxygen within the breathing loop volume after completing the purge maneuver. Statistical analysis comparing the oxygen usage and FiO_2 among the various purge procedures was performed using a split plot (divers vs. submariners) repeated measures ANOVA. Post hoc analysis was conducted using Tukey's HSD test. Statistical significance was set at $p < 0.05$.

Results

Pre-test leak testing

Initial unmanned leak testing of the three units demonstrated significant leaks in all units. One of the main sources of the leaks occurred at the connection between the breathing hoses and the valve main body and the T-assembly mouthpiece. It was found that particular care should be exercised when attaching the breathing hoses to the main body and T-assembly since it is very easy to crimp or displace/push the O-rings out of their grooves when engaging the hoses. Even when the breathing hoses were attached and all the O-rings were seated properly, small leaks were still observed around the sides of the ends of the breathing hoses. These leaks were likely the result of the inside surface of the breathing hose having a slightly indented spiral surface at each end that prevented a good seal with the O-rings. Breathing hoses with a smoother inside bore at the ends would likely provide a better seal. Alternatively, zip ties or hose clamps could be used to prevent leaks at the ends of the hoses.

One of the units was also found to have a leak problem following insertion of the CO₂ absorbent canister into the valve main body of the unit. On inspection of this unit it was found that one or more of the double O-rings on the inside of the valve main body where CO₂ absorbent canister engages the main body became dislodged when the canister was inserted. The problem with the displacement of these O-rings was only evident through leak testing or when the canister was removed. This problem occurred in only one of the three MBS 2000 units tested. However, in several cases when this unit was used in the manned trials the canister fell out of the main body as a result of the O-rings in the valve body being displaced by the canister. It should be noted that the three molded main bodies supplied from Dive Labs Inc. did not have a retaining clip for the canister as in the previous main body version. According to the manufacturer this retaining clip will be included on the new molded main bodies.

Two of the units were also found to have leaks at the point of insertion of the regulator into the main valve body which were resolved by disassembling the regulator from the main valve body, rapping teflon tape around the end of the regulator insert, and then reassembling. Other sources of leaks included the canister lid O-ring. On initial leak testing of the supplied canisters it was found that a significant number of the canisters leaked at the joint between the canister lid and canister bucket. All the canisters were therefore disassembled by removing the holding screws fastening the lids to the buckets and then the canister lid O-ring was lightly lubricated with Christo Lube® prior to reassembly. During reassembly care was exercised to avoid over tightening the holding screws. The above procedure was sufficient to prevent further leaks from occurring around the canister lid O-ring. It should be noted that after prolonged storage this procedure might need to be repeated if the O-ring lube has dried out.

When air was added to the closed circuit breathing loop using the calibrated syringe the pressure within the breathing loop increased once the volume exceeded 4 liters. Due to the high elastance of the new vinyl breathing bags, further increases in volume beyond 4 liters resulted in large increases in internal rig pressure. With 6 liters of air added to the breathing loop pressures reached 73 cmH₂O. Pressures in excess of 144 cmH₂O (the maximum upper range of the pressure transducer) could be applied to the breathing circuit without resulting in catastrophic failure or separation of the main valve body, T-assembly end caps, breathing hoses or breathing bags at their O-ring connections.

Purge procedures

The mean ambient temperature and pressure during testing was 24.6 °C and 765 mmHg, respectively. The preferred purge procedure (in terms of ease of purge) among the 18 subjects was the CR15 (9/18) followed by the CR purge (6/18). The remaining 3 subjects voted for the MVC as the preferred purge procedure. Results comparing the different purge procedures for mass of oxygen used, volume of oxygen used and the inspired fraction of oxygen attained after each purge are shown in Figures 2, 3 and 4 respectively.

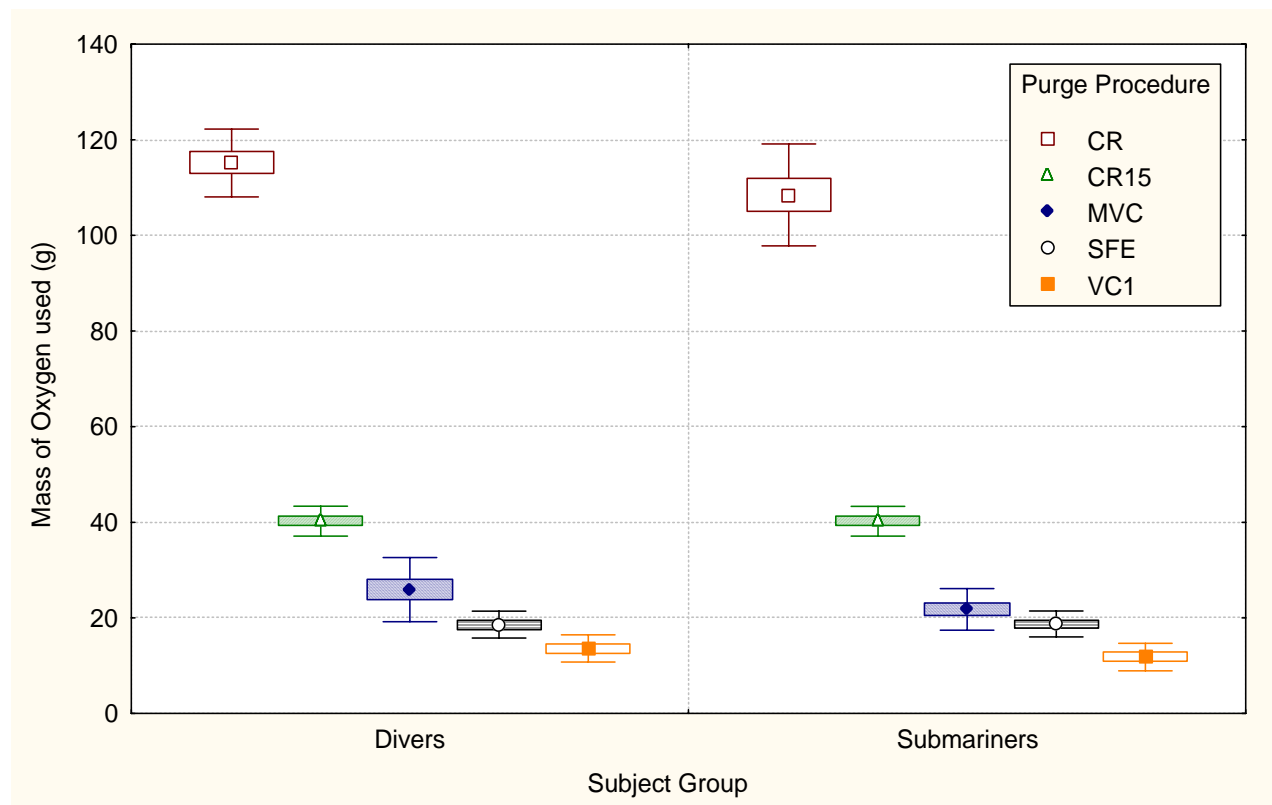


Figure 2: Average mass of oxygen used per subject during the different purge procedures. See text for description of purge procedures. Data are means with Box = mean \pm SE, Whisker = mean \pm SD. $n = 9$ for all data points.

Statistical analysis of the mass of oxygen used over the 6-minute test revealed no difference between submariners and divers ($p=0.076$), but a significant difference in the amount of O_2 used between the different purge procedures ($p<0.00001$). All post hoc pair wise comparisons were significant ($p<0.05$). The order of the purge procedures from highest mass of oxygen used to lowest was CR, CR15, MVC, SFE, VC1. Note that the mass of oxygen used is for the entire 6 min test period. During the MVC purge procedures the number of vital capacity maneuvers was different for different subjects and ranged from 2 vital capacity purges to 6 vital capacity purges. (mean number of VC maneuvers = 3.8 and 4.6 for the divers and submariners, respectively).

Figure 3 shows the average volume of oxygen used for each purge procedure based upon changes in bottle pressure between the start of the test and approximately 30 seconds following completion of each purge procedure. Note that these volumes include the volume of oxygen in the rig as well as that vented to the atmosphere. Estimates of the volume of oxygen vented to the atmosphere will be between 4.8 and 6 l lower than the above volumes. These latter figures are based upon estimates of the volume of oxygen in the rig ranging from that equivalent to the mean VC to 6 l for the entire breathing bag volume. MVC1, MVC2, and MVC3 reflect the volume of oxygen used following each successive VC maneuver. Additional MVC data points are omitted due to the decreasing n. Statistical analysis revealed that when the above volumes are averaged across the 7 different purge data points the divers used approximately 3 l more oxygen than the submariners ($p < 0.05$). The interaction between purge procedure and subject group was not significant ($p = 0.10$). As predicted, the CR15 used close to one third the volume of that needed for the CR purge procedure ($p < 0.001$). The volume of O_2 used during the CR and CR15 purges indicate that the regulator provided a flow close to 60 l/min when the regulator purge valve was activated during the purge procedures. The volume of O_2 used during the VC1, MVC1 and MVC2 purge procedures were statistically similar (mean over both subject groups = 7.7, 6.4 and 9.9 liters, respectively) and were the lowest of the 7 purge procedures analyzed. The SFE and MVC3 purge procedures used a similar amount of oxygen as each other (11.7 vs. 13.1 l, respectively; $p = 0.85$) but both purges used a greater volume of oxygen than the MVC1 and VC1 purge procedures.

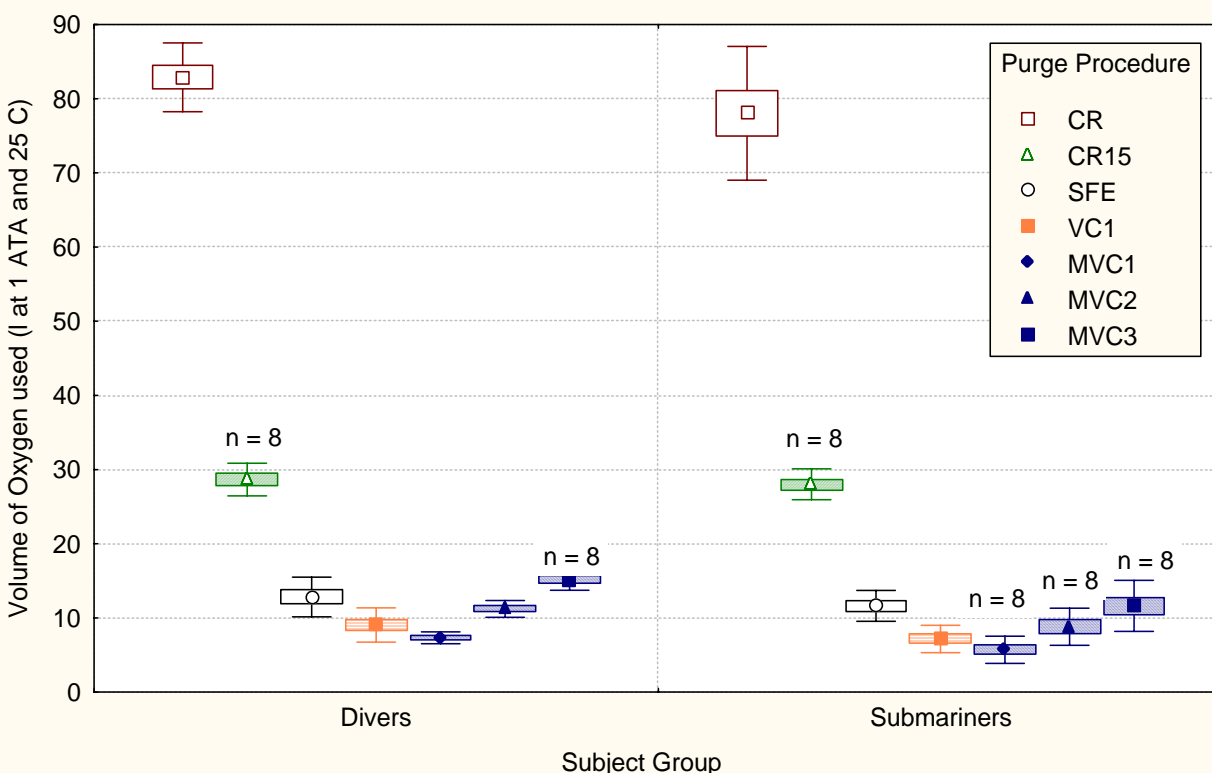


Figure 3: Average volume of oxygen used per subject for each purge procedure. See text for description of purge procedures. Data are means with Box = mean \pm SE, Whisker = mean \pm SD. $n = 9$ except as where noted.

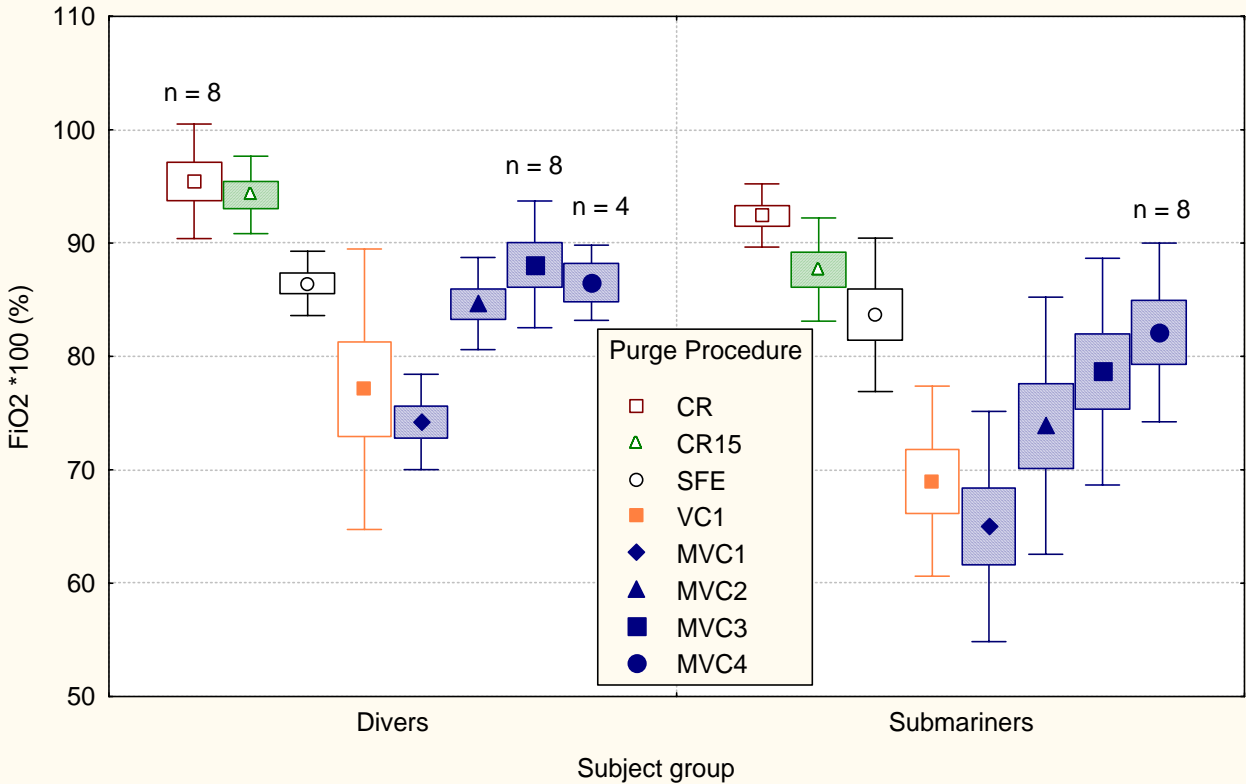


Figure 4: Inspired fraction of oxygen 30 s after completing the different purge procedures for the diver and submariner groups. See text for description of purge procedures. Data are means with Box = mean \pm SE, Whisker = mean \pm SD. n = 9 except as where noted.

Analysis of the FiO_2 data shown in Fig 4 revealed that the divers on average achieved a higher FiO_2 than the submariners (0.85 vs. 0.79 $p < 0.01$). The interaction between subject group and purge procedure was not significant ($p = 0.71$) which indicates that the higher FiO_2 of the divers was evident throughout the different purge procedures. Only the CR and CR15 purge procedures were able to raise the mean FiO_2 above 0.90 (CR = 0.95, CR15 = 0.91, Tukey's paired comparison $p = 0.67$). The next highest FiO_2 was the SFE purge procedure (mean $\text{FiO}_2 = 0.85$), which was significantly lower than the CR FiO_2 ($p < 0.001$) but statistically similar to the CR15 FiO_2 ($p = 0.11$). As expected the VC1 and MVC1 achieved the lowest FiO_2 (0.72 and 0.69 respectively, Tukey's paired comparison $p = 0.94$). MVC2 significantly raised the MV1 FiO_2 by 0.09 to 0.79 ($p < 0.01$) while MVC3 only achieved a 0.04 increase in FiO_2 above that achieved following the MVC2 purge ($p = 0.55$). It should be noted that 3 divers and 6 submariners did not attain an $\text{FiO}_2 > 0.90$ during the MVC maneuvers.

Mathematic model for the calculation of oxygen concentration in the closed-circuit breathing loop of the MBS 2000 following a purge

Neubauer et al., (1997) described a mathematical model that predicts oxygen concentration inside the LAR V closed circuit oxygen rebreathing apparatus after a pre-breathing procedure. Their model assumes that the change in oxygen concentration after each purge procedure will be proportional to the difference between the oxygen concentration reached and the theoretical maximum value and can be characterized by a mathematical equation similar to that, which describes dilution processes where there is a logarithmical approach to a maximum value. Using the general form of their equation the mean data in Fig 5 were fit to the model shown below:

Equation 1
$$O_{2n} = O_{20} + (O_{2max} - O_{20})(1 - e^{-kn})$$

Where:

n = number of Vital Capacity purges

k = coefficient = 0.518

O_{20} = FiO_2 (%) at the beginning of denitrogenation, n=0.

O_{2n} = FiO_2 (%) after n purges.

O_{2max} = theoretical maximum value for FiO_2 (%) = 94%:

The maximum theoretic value for FiO_2 within the MBS 2000 was assumed to be 0.94. This was based on the assumption that the gas within the breathing circuit will become 100% saturated with water vapor at a temperature close to 37 °C (i.e. water vapor pressure at 37 °C for a gas 100% saturated with water vapor = 47 mmHg which at 1 ATA (760 mm Hg) gives a water vapor fraction of 0.06 or 6%). The coefficient k is related to the volume of the breathing purges and the sum of the dead space of the lungs and rig and was determined using non-linear estimation with a quasi-Newtonian algorithm and a least squares loss function. Using this regression technique k was found to be 0.518 with the r^2 for the model fit = 99.66% and standard error = 0.0197 (p<0.00001). The above value for k was found to be almost identical to that found for the LAR V (k= 0.5) by Neubauer et al., (1997).

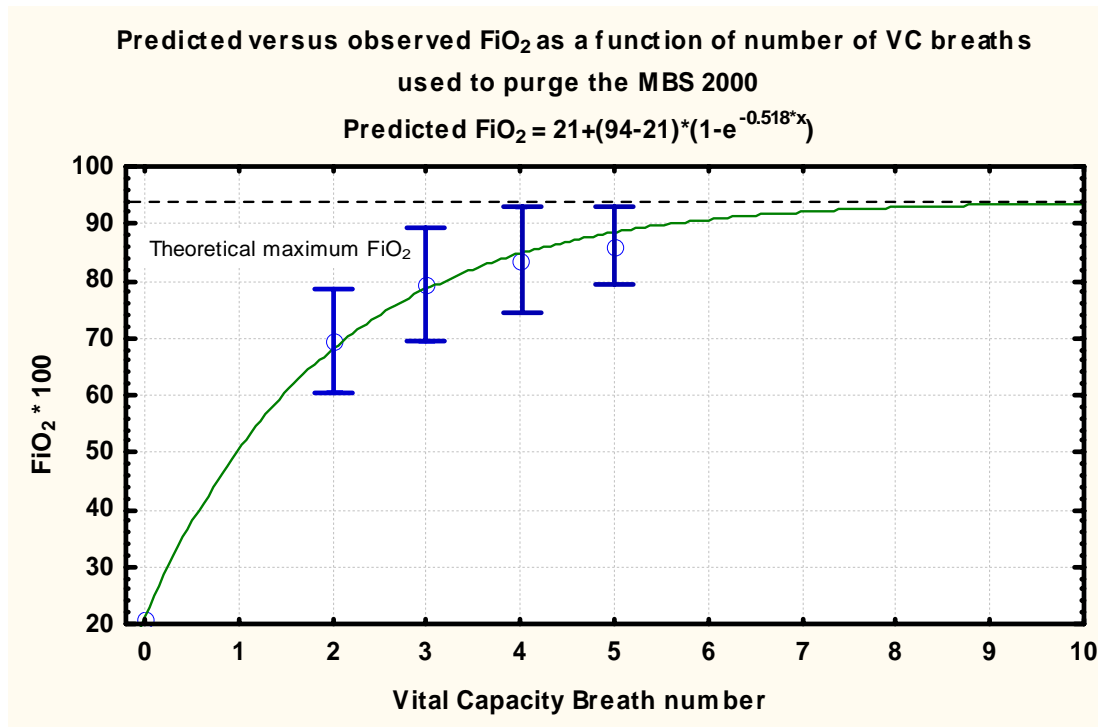


Figure 5: Predicted (green curve) vs. observed (blue data points) FiO_2 as a function of the number of VC purges for the submariners and divers combined. Observed data points are means \pm SD (n=18). A few subjects did not contribute to the mean FiO_2 for purges 3 and 4 because they had already attained an $\text{FiO}_2 > 90\%$. To avoid underestimating the mean FiO_2 for these latter purges these subjects were assigned an FiO_2 equal to their final FiO_2 achieved during purge 2 or purge 3 prior to fitting the data with a model similar to that described by Neubauer et al., (1997) (see text above).

Discussion

The results above indicate that in the three MBS 2000 units tested there were a number of areas where leaks were observed. Although most of these leaks were identified and corrected prior to testing it is possible that minor leaks still existed that may have reduced the efficiency of the purge procedures. The most notable leaks were around the sides of the mask during the VC purge maneuvers. Early experience with using the overpressure relief toggle valve indicated that the size of the orifice for the overpressure relief valve when toggled open was too small to provide adequate flow to prevent a high positive pressure build up in the rig during exhalation. This would tend to reduce the efficiency of purging the exhaled side of the breathing circuit. Since most of the exhaled breath passed around the sides of the oral nasal mask during exhalation during the purge, even when the over pressure relief valve was open, it was decided not to operate the toggle pressure relief valve for the CR15 purge procedure.

Unlike the previous rubber breathing bags which were highly compliant and occasionally burst when over pressurized (White et al., 2000) the urethane coated nylon breathing bags were much less compliant and were able to withstand high pressures without breaking or leaking. As mentioned above when the internal pressure in the breathing circuit exceeded that of the ambient pressure, excess gas leaked around the sides of the oral nasal mask during exhalation rather than bursting the bags or causing separation at any of the press connect joints. One notable advantage of the new breathing bags is that the nylon material, unlike the original rubber breathing bags, is less likely to degrade during storage. After prolonged storage of the rubber breathing bags the rubber was found to degrade, resulting in tiny pinholes that were a potential source of leaks (Mike Ward, personal communication). Furthermore, an old rubber breathing bag used in the original 2000 acceptance testing trials was found to be completely degraded and unusable in 2004. Further testing of the nylon bags is recommended to determine the contribution of any Nitrogen diffusion across the nylon material to the overall leakage problem for the MBS 2000 unit.

Subjects also reported leaks of ambient air into the breathing circuit around the sides of the oral nasal mask during the inspiratory phase of the VC purge procedures. This was particularly noticeable if the inspiratory VC was performed vigorously and was due to the large negative pressure that developed as a result of the low over bottom pressure setting for the second stage regulator. It should be noted that this problem may be exacerbated when using the units at greater than 1 ATA due to increases in gas density at depth. These mask leaks could be minimized by either increasing the second stage over bottom pressure, increasing the size of the orifice for flow in the regulator, instructing the subject to perform the VC breaths slowly, or replacing the oral nasal mask with a T-bit and nose clip.

When a limited number of VC breaths are used to purge the MBS 2000 the efficiency of the purge procedure will depend not only upon any inspiratory leaks as mentioned above but also on the ability of the subject to perform effective VC breaths. It is of note that for a given number of VC purges the divers attained a higher FiO_2 than the submariners but also used more oxygen during the purge procedure. This difference in purge efficiency between the two groups likely reflects the familiarity that divers have with various forms of breathing apparatus and the fact that they were better able to perform the VC maneuvers and maintain good mask management (seal) than the submariners. It should be noted that if the survivors of an actual DISSUB rescue experience significant smoke or toxic gas inhalation their ability to perform effective VC maneuvers for the purge may be compromised. This will result in a less efficient purge and thus a lower initial starting FiO_2 .

The mean volume of oxygen used (i.e. 11.7 liters) and the subsequent FiO_2 obtained following the SFE purge procedure in the present study (i.e. 0.85) are identical to the values reported by Butler and Thalmann (1984) for the standard purge procedure for the LAR V. The standard purge procedure for the LAR V, involves three fill empty cycles, but was not however, recommended for operational use in the U.S. Navy because: (a) high oxygen levels are not required to prevent hypoxia, (b) high oxygen levels increase the probability of encountering central nervous system oxygen toxicity and, (c) unnecessary extra fill/empty cycles consume additional oxygen, thus depleting the gas supply in the UBA (Butler and Thalmann, 1984).

Consequently, Butler and Thalmann chose a single fill/purge procedure that resulted in an average FiO_2 of 0.74 as their optimum purge procedure for the LAR V.

While minimizing the volume of oxygen used during the purge was one of the objectives of the current study, unlike operation requirements for the LAR V, the primary function of the MBS 2000 is to provide an FiO_2 as close to 1.0 as possible. Thus the optimal purge procedure required for a closed-circuit O_2 rebreather used in a treatment/decompression will be by design different than that required for purging an underwater closed-circuit rebreather such as the LAR V.

Of the entire purge procedures tested the simplest and most preferred purge procedure was found to be the CR15. The CR15 and CR purge procedures were also the only purge procedures capable of achieving a starting $\text{FiO}_2 > 0.90$. Although the CR and CR15 purge achieved a similar FiO_2 , the CR15 purge achieved this using approximately two thirds less volume of oxygen than the CR purge. According to the mathematical model shown in Fig 5, at least 6 VC purges are required to raise the FiO_2 in the MBS 2000 from 0.21 to > 0.90 . The requisite number of VC's is achieved during the CR and CR15 purge procedures but not during the SFE, VC1 or for the MVC in which less than 6 VC's are performed. Using the group mean ($n=18$) VC of 5.1 liters, gives a total volume of oxygen used for 6 VC purges of 30.6 liters BTPS at 1 ATA. This value is similar to the group mean volume of oxygen used for the CR15 purge (28.4 liters at 1 ATA and 25 °C).

The mathematical model shown in Equation 1 can be rearranged to determine the number of VC breaths required to purge the rig to a $\text{FiO}_2 > 0.90$ from any starting FiO_2 . This information is useful for conditions where a subject needs to re-purge their rig from a starting FiO_2 other than 0.21 such as after a prolonged rebreathing period where nitrogen off-gassing will have reduced the FiO_2 within the breathing loop below the initial post purge value. For example if the FiO_2 within the breathing loop has dropped to 0.80 and the goal of a re-purge is to achieve an $\text{FiO}_2 > 0.90$ the mathematical model shown in Fig 5 shows that at least 3 VC purges are required. This suggests that if 0.80 is used as the FiO_2 limit to initiate a re-purge then a single 15 sec CR15 purge should be sufficient to bring the FiO_2 within the breathing circuit back to > 0.90 .

A final comment should be mentioned on the use of the T-7 oxygen sensor in monitoring the oxygen fraction within the MBS 2000 breathing circuit. Although the specification for this oxygen cell indicates an accuracy of $\pm 2\%$ of full scale, use of these sensors under conditions where there are large changes in water vapor pressure and gas temperature can lead to substantial errors in the measured oxygen concentration. In the current experiments post purge calibrations indicated that the combined effects of increases in water vapor pressure and gas temperature can result in an underestimation of up to 10% in the actual (dry) fraction of oxygen in the breathing circuit. These changes in post calibration FiO_2 values were most notable following the final two purge procedures conducted, in which the subject had rebreathed on the unit for a combined time of approximately 20 minutes. Any bias in FiO_2 values caused by this phenomenon was accounted for by randomizing the order of presentation of the different purge procedures.

Although a fixed vapor pressure of 6% may be assumed for the purposes of estimating the dry oxygen fraction based upon 100% saturation of water vapor at 37 °C, it should be noted that it takes some time for the water vapor and gas temperature within the breathing circuit to reach

these values. Furthermore, evidence from the leak test trials (see section II below) suggested that after 70 min of breathing on the MBS 2000 the gas temperature at the oxygen cell may exceed 37 °C. Consequently, if a fixed 6% vapor pressure is assumed the actual dry FiO_2 in the breathing circuit will tend to be overestimated during the early stages of a treatment (i.e. during the first 20 mins) and underestimated once the rig is fully saturated and warmed up. Errors in FiO_2 may occur at these high vapor pressures due to water vapor condensing on the cell membrane, which will slow the rate of diffusion of oxygen into the cell and reduce the cell's responsiveness. Although, the T-7 has an in-built temperature compensation for FiO_2 correction, the thermistors sensing the cell's temperature are located in the posterior compartment of the cell. In the current configuration (see Fig 1) the temperature of the gas stream sensed by T-7 cell will likely be higher than the ambient air surrounding the MBS 2000, which will lead to additional errors in FiO_2 determination. If an oxygen cell is to be included within the MBS 2000 unit in a future model it is recommended that the entire oxygen cell be located within the gas stream to avoid this latter potential error.

Conclusions

- Divers use more oxygen than submariners during the purge procedures but attain a higher FiO_2 than the submariners.
- The simplest and most preferred purge procedure is the CR15.
- The CR and CR15 purge procedures were the only procedures tested that achieved a starting $\text{FiO}_2 > 0.90$.
- The CR and CR15 purge procedures achieve a similar FiO_2 , but the CR15 purge achieves this using approximately two thirds less oxygen than the CR purge.
- The SFE purge uses approximately 40% of the oxygen used by the CR15 at the expense of a 6% non-significant decrease in the starting FiO_2 .
- Use of the overpressure valve is problematic due to the small orifice causing a high backpressure leading to most of the exhaled breath escaping around the sides of the mask rather than through the rig during the CR purge procedure.
- The SFE and MVC3 purge procedures use a similar volume of oxygen and achieve a similar starting FiO_2 .
- A mathematical model of the change in FiO_2 following each VC purge predicts that at least 6 VC purges are required to raise the FiO_2 in the MBS 2000 from 0.21 to > 0.90 .

Comments and Recommendations

Many subjects had problems locating and operating the overpressure valve correctly during the different purge procedures. Accidentally forgetting to let go of the overpressure valve during the SFE or VC1 purge procedures led to ambient air entering the rig through the overpressure valve during an inspiration. This dramatically reduced the effectiveness of the purge procedure and led to a low initial FiO_2 for some of the subjects. Due to the complexities of operating the overpressure relieve valve while at the same time squeezing the breathing bags the SFE and VC1 purges are not recommended for submariners or individuals who have minimal training on using the rig. For untrained individuals the CR15 offers a compromise for ease of use and oxygen consumption. If volume of purge is critical the SFE purge offers a compromise between maximizing the starting FiO_2 and minimizing oxygen usage. However the difficulties described above with the overpressure relieve valve likely reduce the effectiveness of this procedure for purging the rig. One possible solution to the use of the overpressure valve for purging the rig is to add a Y-valve between the end cap on the exhalation side of the main body assembly and the end of the exhalation hose. During emptying of the bags the Y-valve would be rotated to direct the expired gas to the atmosphere. This would allow the subject to purge their lungs as well as the expired side of the rig without having to operate the overpressure valve or to operate the plunger valve on the facemask. Once the breathing bags have been emptied and the rig and lungs fully purged the Y-valve would be rotated to direct the exhaled breath to the closed circuit. The only portion of the rig that would not be purged with the use of a Y-valve would be the CO_2 canister.

After prolonged storage of a prefilled CO_2 absorbent canister, or when a new CO_2 absorbent canister is used, it is necessary to de-dust the canister before use. This can be achieved by forcing cool air with a hairdryer into the exhalation port of the canister and allowing the dust to escape from the inhalation port. Although the above procedure was done prior to the purge tests it was noted that some Sofnolime™ dust was still inhaled during the initial VC purges. This resulted in an irritation/burning/tickling sensation of the throat that persisted for a considerable amount of time following the purge test. Irritation from Sofnolime™ dust could be minimized by incorporating a micro pore filter on the inspired side of the breathing circuit or by redesigning the canisters to accept solid CO_2 absorbent rolls such as those developed by Micropore Inc, Newark, DE. Besides eliminating the dusting issue, adoption of a solid CO_2 absorbent would also facilitate emptying and refilling of the canisters, with loose Sofnolime™ which is a currently a time consuming and tricky procedure. The disadvantage to using the Micropore absorbent is the higher cost for the absorbent canisters and additional test and development time required to determine canister duration. A preliminary evaluation of the Engineered Medical Systems, Inc. (EMS)/Micropore closed-circuit oxygen rebreather conducted at Duke University indicates that an ExtendAir Micropore canister can last up to 8 hours before reaching 'breakthrough' (0.005 surface equivalent value [SEV] or 3.8 mm Hg CO_2 measured at the exit of the CO_2 absorbent canister) (Pollock et al., 2003). However, adoption of the Micropore absorbent may require remolding the main body of the MBS 2000 in order to accept the Micropore canister.

II. 1 ATA Leak Rate Tests

Objectives

- I. Obtain oxygen consumption and rig leakage data that will allow calculation of the total volume of oxygen needed to support an operation.
- II. Determine the average number of purges required to maintain the oxygen level in the breathing loop above 75%, above 80%, above 85% and above 90% during a 60 min breathing period following an initial purge at 0 fsw.
- III. Determine mask leak rates in shaved and unshaven subjects at 1 ATA.
- IV. During the purge procedures and while breathing on the MBS 2000 closed circuit at 1 ATA determine the rate of build up of oxygen in the enclosed atmosphere of the chamber over a 60 min period.

Methods

Subjects

Subjects were 9 submariners and 9 divers. All but one of the diver subjects had participated in the previous trials assessing the effectiveness of different purge procedures for the MBS 2000 (see previous preliminary report). Subjects were briefed on the studies objective and provided informed consent.

Apparatus

All leak trials were conducted inside the main lock of NSMRL's recompression chamber (BUSHIPS Stock Number S23-C-32950-200). An acrylic plate was mounted to the inside of the medical lock and provided a pass through for three oxygen supply lines, a gas sample port, a return gas sample port and three electrical wire penetrations for monitoring the output from the oxygen cell for each MBS 2000 unit (see Fig 6). Once the inner chamber hatch was closed, the volume within the inner lock of the chamber was sealed from the external atmosphere allowing any changes in O₂ and CO₂ gas composition within isolated volume of the inner lock of recompression chamber to be monitored.

Each subject was provided with a leak-tested MBS 2000 closed-circuit oxygen rebreather that had the same configuration as that described in section I above. Instead of using the T-7 oxygen cell as described above, oxygen levels within the MBS 2000 closed circuit were monitored continuously using an R-17D oxygen sensor (Teledyne Analytical Instruments, Industry, CA) inserted into the inspired side of the main body assembly using the same custom designed coupling. The R-17D oxygen sensor is commonly used to measure oxygen concentration in closed-circuit rebreathers and works on the same principle as the T-7 but does not contain a metal mesh membrane. By eliminating the metal membrane it was hoped to reduce water condensation issues in the cell that would reduce its responsiveness to changes in oxygen partial pressure. Output from the oxygen sensor was amplified using a Gould DC amplifier before being sampled at 50 Hz using a BIOPAC A/D computer system.



Figure 6: A photograph of the experimental set up and apparatus used during the leak test trials. The M9 oxygen cylinders used to provide high pressure O_2 to the MBS 2000 units are shown in the foreground. Pass throughs for the three oxygen supply lines, a gas sample line and return gas sample line, as well as, three electrical wires used for monitoring the output of the O_2 cells are shown penetrating the chamber through an acrylic plate mounted to the inside of the medical lock.

The FO_2 and FCO_2 within the chamber atmosphere were monitored continuously using an S-3A oxygen analyzer (Applied Electrochemistry) and CD-3A CO_2 analyzer (Applied Electrochemistry), respectively. Output from the O_2 and CO_2 analyzers were also sampled and stored on computer disc using the Biopac A/D data acquisition system. The above analyzers were used to periodically check the FiO_2 and $FiCO_2$ in each MBS 2000 unit. This was achieved by attaching the chamber gas sample line to the quick connect gas sample port on the main body of the MBS 2000 unit. Gas samples from each unit were drawn for approximately 30 s at a flow rate of 125 ml/min at the following minute intervals from the start of the test: 5, 10, 20, 30, 40, 50, 55, and 68 min. These periodic gas samples permitted the FiO_2 readings from the R-17D oxygen sensor to be corrected for water vapor pressure and errors due to fluctuations in gas temperature within the breathing circuit. Water vapor corrections for gas analysis were achieved by passing the gas samples through a METM-Series moisture exchanger. This device uses Nafion[®] membrane tubing technology to transfer water to or from a gas stream. In drying applications, ME-Series moisture exchangers transfer water vapor from a wet gas stream into the

surrounding atmosphere. Drying is complete when the sample humidity level is equal to the ambient humidity level. For humidification, the ME-Series will transfer water vapor from the atmosphere to a dry gas flowing within the tubing. Initial calibration of the O₂ and CO₂ analyzers was conducted using the same sample line set up as that used for measuring the chamber atmosphere and the gas fractions within the MBS 2000 breathing circuit. The moisture exchanger thus humidified the dry calibration gases to the same level as that in the laboratory atmosphere. Since the moisture exchanger dehumidify the gas samples from the chamber atmosphere and the MBS 2000 breathing circuits to the same level as in that used during calibration of the analyzers no further corrections were required to account for water vapor pressure.

At the end of each chamber trial the peak temperature of the gas exiting the CO₂ scrubber of each MBS 2000 unit was measured using a Digi-Sense thermocouple thermometer (Cole Palmer). These gas temperature measurements were achieved by removing the O₂ cell, placing the head of the thermocouple into the O₂ sensor port and expiring into the unit to flow gas through the CO₂ scrubber.

Procedures

Each subject conducted two leak test trials on separate days. The leak tests were conducted at 1 ATA and involved 60 minutes of rebreathing followed by a 5-minute air break and a final 5 minutes of rebreathing. For the first trial, subjects were clean-shaven (CT). The second trial was conducted after the subjects had abstained from shaving for between 7 and 14 days (UT). Only one subject conducted the unshaven trial before the clean-shaven trial. The majority of trials were conducted with three subjects at a time seated next to each other in the main lock of the recompression chamber as shown in Fig 7. After the subjects were seated in the recompression chamber the inner hatch was dogged shut and each subject commenced purging using the following procedure:

Purge procedure

After fully exhaling to residual volume the subject dons the MBS 2000 mask and conducts a 15 sec purge by pressing the MBS 2000 regulator purge valve. During the 15 sec purge the subject conducts 3 deep breaths allowing the exhaled portion of the breath to escape around the sides of the oral nasal mask. After the 15 sec purge the subject releases the regulator and breathes normally for 30 s. The above 15 sec purge procedure is repeated one more time before commencing normal breathing on the unit.

The initial purge as well as any additional purges during the 70-min test period followed the same procedure. Each purge was initiated on the command of the experimenter and timed by a stopwatch. Subjects were instructed to re-purge if their FiO₂ dropped below 0.70. A re-purge was also performed at minute 65 following the 5-min air break. During the air break subjects took off their mask and breathed the chamber atmosphere. Prior to doffing the mask the slide valve piston on the mask "T" assembly was inserted to isolate the breathing loop and prevent contamination of the breathing loop with chamber atmosphere.

If more than one series of trials were conducted on the same day, the chamber atmosphere was ventilated between trials using a large fan until the FO₂, FCO₂ and water vapor pressure within the inner lock of the chamber had returned to the initial conditions.



Figure 7: Three subjects undergoing leak testing in the main lock of NSMRL's treatment chamber. The O₂ and CO₂ concentration in the chamber atmosphere was monitored via a gas sample line the end of which was placed at chamber mid level next to the acrylic plate shown in the center of the picture.

Analysis

The volume of oxygen used at the end of the first 60 min rebreathing period was determined for each subject from the change in bottle pressure. The rate of decline in FiO₂ after the initial purge was determined for each subject by measuring the time taken for the FiO₂ to reach the following levels, 0.90, 0.85, 0.80, and 0.75. Statistical analysis comparing the volume of oxygen used over the 60 min during the clean shaven and bearded trials was performed using a split plot (divers vs. submariners) two-way repeated measures ANOVA (clean shaven vs. bearded trial and degree of beard growth). Post hoc analysis was conducted using Tukey's HSD test. All volumes are presented at standard temperature and pressure (i.e. 1 ATA and 25 °C). Data are presented as means ± SD except as where noted.

Beard growth was initially rated on a 0 to 9 point scale with 0 representing clean-shaven and 9 representing a full heavy (thick) beard growth. For the purpose of statistical analysis beard growth ratings were further reduced down to 3 categories: light growth (beard ratings 1, 2 and 3), medium growth (ratings 4, 5 and 6) and heavy growth (beard ratings 7, 8 and 9). During each trial the FiO₂ just prior to the onset of the re-purge as well as the number of purges performed by

each subject was recorded. Differences in the number of purges and oxygen usage between trials for different levels of beard growth (light, medium and heavy) were analyzed using Kruskal-Wallis ANOVA by ranks. Wilcoxon Matched Pairs Test was used to compare the number of purges between CT and UT for the different beard categories. Statistical significance was set at $p < 0.05$ for all tests.

Results

Ambient Conditions

The mean \pm SD for ambient pressure, laboratory temperature and humidity during the leak test trials were 766 ± 15 mmHg, 24.3 ± 2.1 °C and $23 \pm 6\%$, respectively. As the chamber remained isolated from the external atmosphere and was not vented during the trials, the ambient temperature and relative humidity within the inner lock gradually rose over the 70-minute test. After 70 minutes the temperature and humidity in the chamber reached 27.7 ± 1.6 °C and $89 \pm 10\%$, respectively. At the end of the test the temperature of the gas within the breathing loop measured at the oxygen sensor averaged 38.1 °C (SD $= \pm 1.5$ °C) following both the shaved and unshaved trials.

Clean shaven trials

The mean \pm SD for the volume of O₂ used over the first 60 minute breathing period was similar for the divers and submariners (divers $= 76.8 \pm 32.4$ liters, submariners $= 87.1 \pm 29.8$ liters, $p = 0.96$, overall mean \pm SD $= 81.9 \pm 30.7$ liters). The number of additional purges conducted beyond the initial purge during the first 60-minute period ranged from 0 to 5 (mean \pm SD 1.8 ± 1.5 purges). Only three subjects (2 divers and 1 submariner) did not require an additional purge during the 60-minute breathing period. For those subjects that required at least one additional purge ($n=15$), the mean time from the end of the first (initial) purge to commencement of the second purge was 21.3 ± 14.8 min. The mean FiO₂ just prior to the second purge was 0.66 ± 0.07 . Nine subjects required at least two additional purges during the 60 min breathing period. Statistical analysis (paired t-test) of the data from these 9 subjects revealed that the average duration between the first (initial) and second purge (14.5 ± 10.3 min) was similar to that between the end of the second purge and the start of the third purge (17.0 ± 6.9 min, $p = 0.60$). The FiO₂ at the end of the first purge (0.62 ± 0.06) and second purge (0.68 ± 0.03) was also similar ($p=0.056$).

The average time taken for the concentration of oxygen within the closed circuit breathing loop to drop to various FiO₂ levels following the initial purge is shown in Fig 8. Note that one subject only managed to raise the FiO₂ in his MBS 2000 unit to 0.86 following the initial purge. This resulted in 17 rather than 18 subjects contributing to the 0.90 FiO₂ data point in Fig 8. During the first gas-sampling period taken 2.7 min after completing the initial purge it was found that the FiCO₂ in this latter subjects MBS 2000 unit reached a peak level of 0.047. Through the entire test the FiCO₂ within this subjects MBS 2000 unit remained elevated with the mean FiCO₂ ranging between 0.023 and 0.037. This fact contributed to the low FiO₂ noted for this subject following the initial purge. The same phenomenon also occurred with one other subject during a clean-shaven trial. Both problems were attributed to a faulty valve within the mouthpiece rather than breakthrough of CO₂ through the CO₂ absorber since this phenomenon did not reappear when the valve "T" assembly was replaced and the same CO₂ absorbent canister was reused (without refilling). It is also noted in Fig 8 that only 17 subjects contributed to the 0.75 FiO₂ data

point. This was due to the fact that the FiO_2 within one subjects' MBS 2000 unit never dropped to 0.75 throughout the entire 60 minutes. The time point at which the FiO_2 dropped to 0.70 time is not shown since 5 subjects never reached this FiO_2 limit.

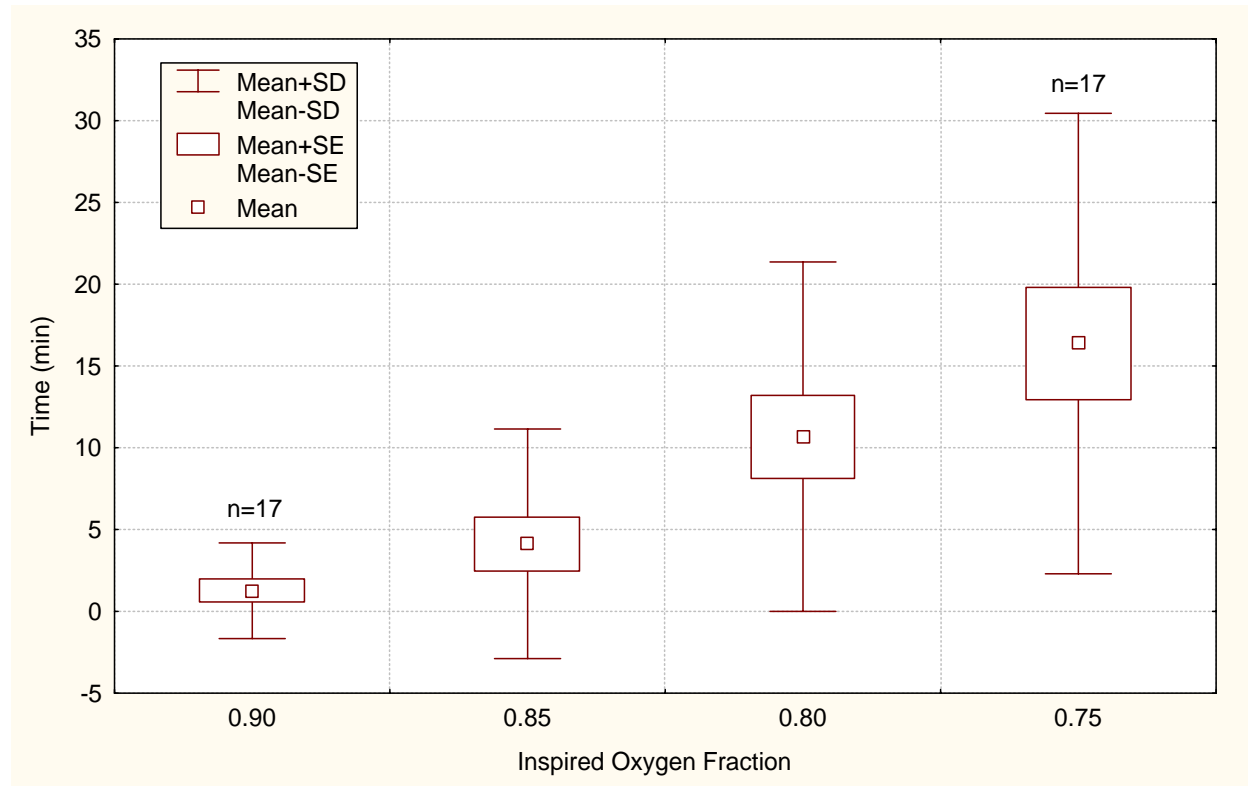


Figure 8: A box and whisker plot showing the average time taken for the concentration of oxygen within the closed circuit breathing loop to drop to various FiO_2 levels following the initial purge. Data are based on n = 18 except as where noted.

A split plot (submariners vs. divers) repeated measure ANOVA on the time for the oxygen concentration within the breathing circuit to reach the four FiO_2 levels (0.90 to 0.75) revealed a significant main effect for FiO_2 level ($p < 0.00001$) but no significant main effect for subject group ($p = 0.49$) or two-way interaction between subject group and FiO_2 level ($p = 0.80$). This indicates that while there are significant differences in the time taken for the FiO_2 to reach the different limits, the submariners and divers took approximately the same time to reach each of the different limits. It should be noted however, that the repeated measures analysis design omits the submariner with the low initial FiO_2 , mentioned above, as well as one of the divers who never attained an FiO_2 of 0.75 from the analysis. In view of the potential bias created by omitting these two subjects from the analysis, Figure 9 divides the data from Figure 8 into separate plots for the submariners and divers.

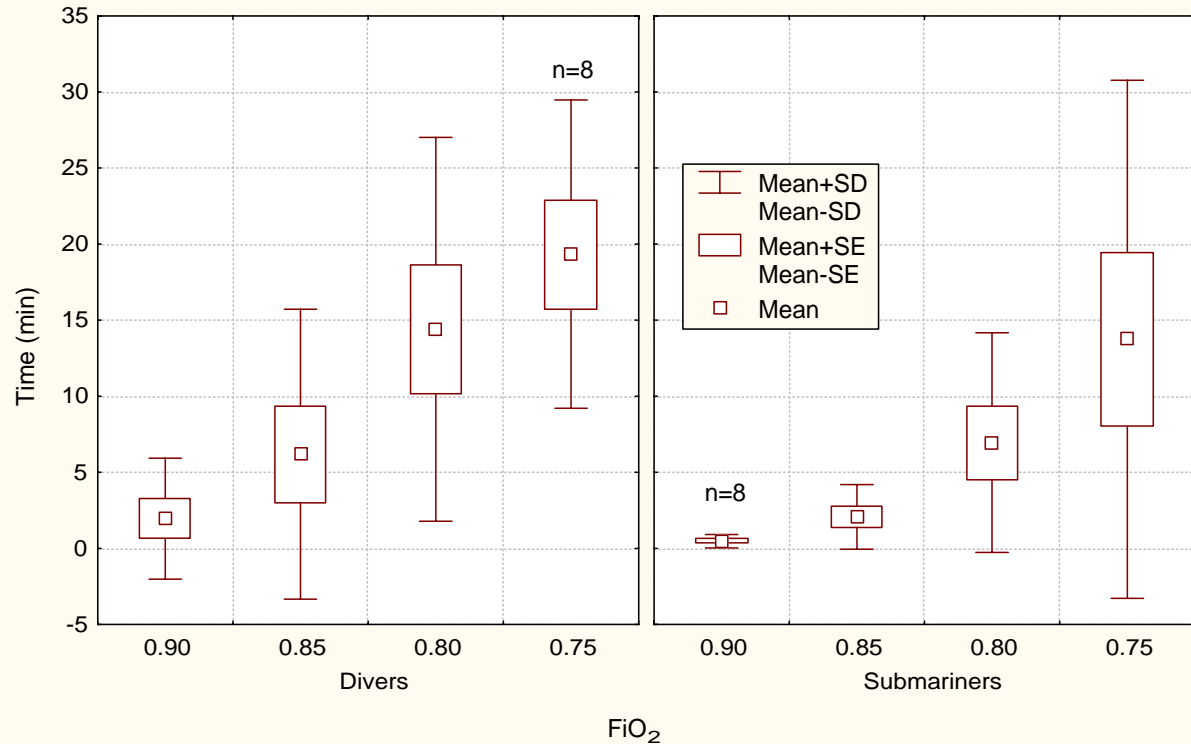


Figure 9: A box and whisker plot showing the average time taken for the concentration of oxygen within the closed circuit breathing loop to drop to various FiO₂ levels following the initial purge for the diver and submariner group. Data are based on n = 9 except as where noted.

Bearded trials

The amount of beard growth after abstaining from shaving for 7 to 14 days showed considerable variability between subjects. The number of subjects classified with light, medium and heavy beard growth is shown in Table 1. The preponderance of submariners tended to lie in the light and moderate categories where as most of the divers fell in the medium and heavy beard growth category. This difference reflects the younger age of the submariner group compared to the diver group. The average number of additional purges performed during the 60 min rebreathing period following the initial purge is also shown for each beard growth category in Table 2. All subjects required at least one additional purge with the maximum number of additional purges reaching 10 in one subject with heavy beard growth. Statistical analysis of the purge data showed no difference in the number of purges between the beard categories for CT ($p = 0.23$) but a significant difference in the number of purges between beard categories during the UT ($p = 0.04$). This difference was primarily the result of a larger number of purges for the heavy beard category compared to the other categories. For the heavy beard category the number of purges during UT was more than triple that during the CT ($p < 0.05$).

The average time from the end of the initial purge to the start of the second purge was 16.2 ± 13.6 min ($n=18$) but was significantly affected by the amount of beard growth ($p < 0.05$). The duration between the first and second purge for subjects with light or medium beard growth was between two and three times longer than for those with heavy beard growth. The mean FiO₂ just

prior to initiating the second purge was 0.66 ± 0.06 which is identical to that recorded during for the clean-shaven trials ($p=0.98$).

Table 3 compares the clean-shaven and bearded leak trials (by beard growth category) for the volume of O₂ used over the first 60-minute breathing period. Although the mean volume of O₂ used was not significantly different from the clean-shaven trials there was a significant interaction for O₂ usage between the clean-shaven and bearded trials and degree of beard growth ($p<0.01$). Subjects with light and medium beard growth used a similar amount of O₂ as in their clean-shaven trials where as those subjects with heavy beard growth used significantly more O₂ than in their clean-shaven trials ($p<0.05$).

Table 1: Numbers of submariners and divers in each category of beard growth

Beard Growth Category	Number of Divers	Number of Submariners	Total number of subjects
Light Growth	1	3	4
Medium Growth	3	4	7
Heavy Growth	5	2	7
Total	9	9	18

Table 2: Numbers of subjects in each beard growth category together with the mean number of additional purges performed following the initial purge during CT and UT trials. (* $p<0.05$)

Beard Growth Category	Number of subjects	Average # of purges: clean shaven (CT)	Average # of purges: bearded (UT)	P value for Wilcoxon Match Pairs Test
Light Growth	4	3.2 ± 2.0	1.5 ± 0.6	0.20
Medium Growth	7	1.4 ± 1.0	2.4 ± 2.5	0.35
Heavy Growth	7	1.4 ± 1.4	5.1 ± 2.7	0.03*
Total	18	1.8 ± 1.5	3.3 ± 2.7	0.11

Table 3: Comparison of the mean \pm SD volume of oxygen used (liters at 1 ATA and 25 °C) during 60 min of rebreathing between the clean-shaven trials and bearded trials separated out by beard growth category. (* $p<0.05$).

Beard Growth Category	Number of subjects	Clean shaven trials	Bearded trials	p value
Light Growth	4	113.6 ± 32.0	71.0 ± 10.7	0.83
Medium Growth	7	73.7 ± 7.7	72.4 ± 34.7	0.94
Heavy Growth	7	72.0 ± 22.8	159.4 ± 58.6	0.04*
Overall mean	18	81.9 ± 30.7	105.9 ± 59.9	0.19

Hypoxia Incident

During one of the leak trials a submariner briefly lost consciousness several minutes after completing an initial purge. The individual had been fully instructed on the correct purge procedure immediately prior to donning the MBS 2000 mask. He had also participated in the first phase of the study (see section I above) four weeks prior to the incident and so had been fully trained on the purge procedure. Examination of his MBS 2000 unit at the time of the incident ruled out rig malfunction as the primary cause of the hypoxia. In a debriefing of the submariner and the other two subjects who conducted the leak test during the same time trial it became apparent that the submariner had performed the purge procedure incorrectly. This conclusion was further supported by analysis of the subject's FiO_2 data, which revealed that the FiO_2 within his MBS 2000 had not been raised above 0.21 immediately following the second 15 sec purge. Eighteen seconds after completing the purge the FiO_2 showed a temporary increase to 0.48 which was likely due to automatically activating the regulator at the end of an inspiration when the breathing bags were fully deflated. However, within 10 sec of this oxygen peak the FiO_2 dropped below 0.25. As the subject continued to rebreathe on the unit further decreases in FiO_2 were more gradual. After four minutes of rebreathing a gas sample line was attached to the rig to check the abnormally low O_2 cell reading. Just as this gas sample was being taken the subject lost consciousness. The MBS 2000 mask was immediately removed from the subject and he regained consciousness within a few seconds of breathing chamber air. Just before the subject lost consciousness the FiO_2 within the MBS 2000 breathing circuit was measured at approximately 0.07.

It became clear from analysis of the data file and reports from the three subjects that the main reason the O_2 content failed to rise following the purge was due to the subject holding the toggle switch open during the entire purge procedure instead of depressing the demand regulator. With the toggle switch depressed most of his inspired breath was drawn through the open toggle switch from the chamber atmosphere resulting in minimal increases in oxygen concentration within the breathing loop. To minimize the future chances of a hypoxia incident it is recommended that the toggle switch be removed from the unit or replaced with a pop-off valve that seals automatically on inhalation and requires minimal subject participation to operate correctly.

Chamber Oxygen Concentration During the Leak Test Trials

Figure 10 shows the change in oxygen concentration in the inner lock of the chamber as a function of the total amount of oxygen used by the subjects. Oxygen usage includes the volume used for purges as well as that used to support the resting metabolic rate of the subjects. The data show a total of 11 leak trials (5 clean shaven and 6 unshaven). Each data point represents the combined cumulative volume of oxygen used by the subject team for a given leak trial at a given time point. The concentration of oxygen in the chamber taken at the start of the trial and before any purges were conducted is given at the 0 volume point on the x-axis. The other data points were taken at minutes 15, 30, 45 and 60. In all but one of the leak trials 3 subjects were tested at the same time (see Fig 7). In the other leak trial only two subjects were tested. In one clean-shaven trial with three subjects the outer hatch of the chamber was closed and the inner hatch was left open. Due to the different chamber volume used in this latter trial the data from this trial was omitted from Fig 10.

The linear regression line shown in Fig 10 predicts that the oxygen concentration in the chamber atmosphere will rise to 25% after a total of 620 liters of oxygen has been used to support purging and resting metabolic rate requirements. The volume of oxygen required to support the resting metabolic rate can be estimated from two divers who after their initial purge did not purge for 60 minutes. After the initial purge these two divers used 20 and 26 liters of oxygen, respectively over a 60 min period. This translates to an oxygen consumption of 0.33 and 0.44 l/min, respectively. If we assume an average oxygen consumption rate of 0.4 l/min the total amount of oxygen consumed by 3 subjects over 60 min = 72 liters. If the volume of oxygen consumed is subtracted from the total amount of oxygen used then according to the data in Fig 10 the estimated amount of oxygen that can be attributed to purges that would raise the oxygen in the chamber atmosphere to 25% would be approximately 548 liters.

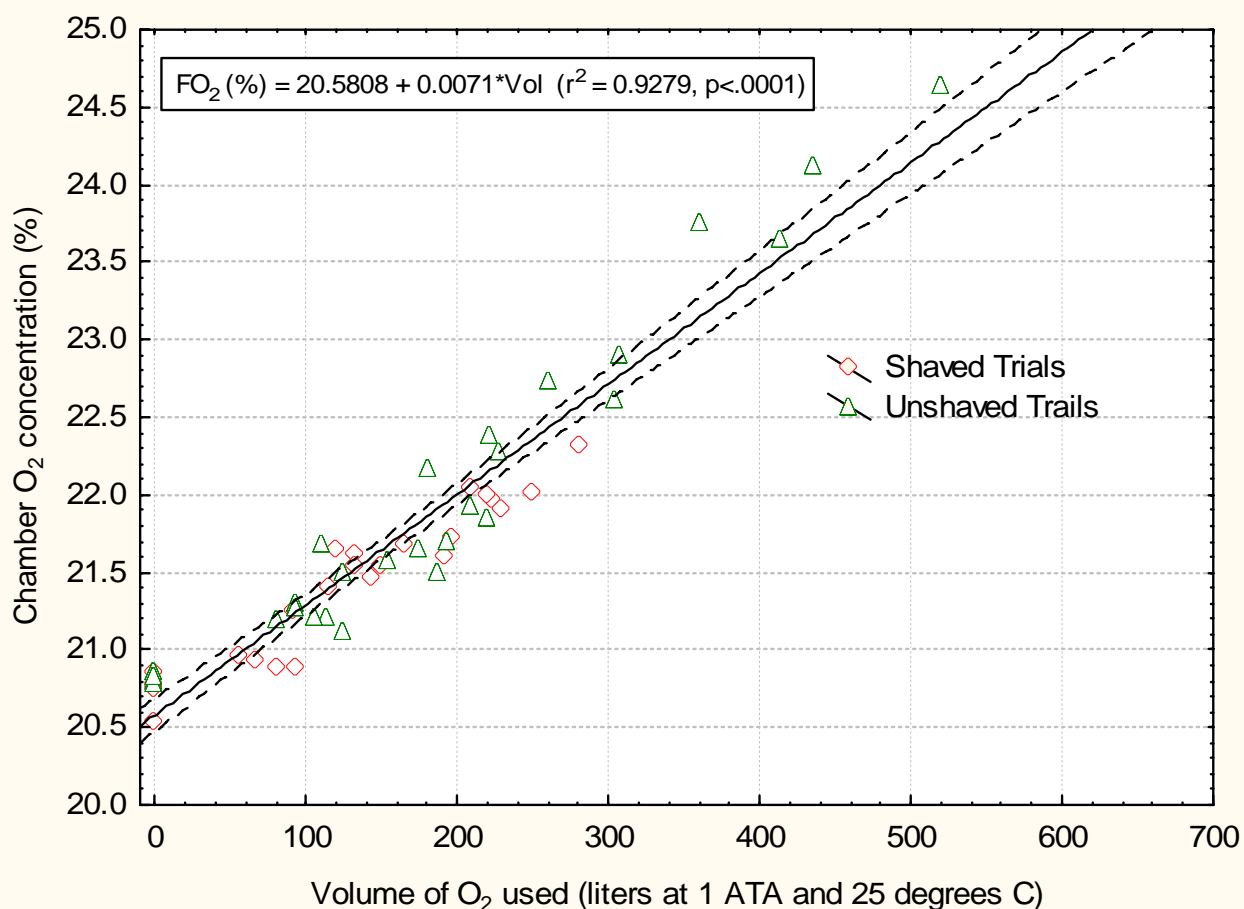


Figure 10: Changes in oxygen concentration in the inner lock of the hyperbaric chamber as a function of the total cumulative volume of oxygen used during individual leak test trials at selected time points. The linear regression and 95% confidence intervals that were fit to these data are also shown. See text for further details.

The volume of oxygen required to raise the chamber oxygen concentration from any given starting fraction to 25% can also be determined theoretically if the volume of the chamber is known. The Pre-Survey Outline Booklet for the NSMRL treatment chamber (BUSHIPS Stock No. S23-C-32950-200) indicates that the inner lock is 307 cuft (8,693 liters). The effective chamber volume will be the total inner lock volume – the volume taken up by occupants. Determination of human body volume for a submariner of average size can be calculated from height and weight using the graphical methods outlined in Sendroy and Collison (1966). Using this graphical method, the calculated body volume for a submariner of average height (179 cm) and weight (85 kg) is 80 liters (2.83 cu. ft.). Thus the effective volume for the inner lock when three people occupy it will be 8,453 liters.

Using the mean oxygen concentration at time zero (i.e. 20.78%) as the starting oxygen concentration and 25.00% as the final oxygen concentration, the increase in fractional oxygen concentration is 0.0422. Assuming that the chamber pressure remains at 1 ATA and there is no temperature change, then the volume of oxygen added to increase the oxygen concentration in the chamber atmosphere to 25% = $0.0422 * 8453 \text{ liters} = 357 \text{ liters}$. This value is 191 liters less than was derived above using the data in Fig 10.

The measured changes in chamber oxygen concentration with oxygen usage clearly overestimate the volume of additional oxygen needed to raise the chamber oxygen content to 25%. The explanation for this observation is that either the chamber O₂ measurements underestimate the true chamber O₂ content and/or that the volume of O₂ used overestimates the amount of oxygen escaping into the chamber atmosphere. Since not all the oxygen used was dumped into the chamber atmosphere, the data in Fig 10 need to be corrected for a) oxygen remaining in the supply lines, b) the volume of oxygen in the subjects lungs and MBS 2000 breathing circuit and c) metabolic oxygen consumption in order to estimate the volume of oxygen dumped to into the chamber atmosphere. The data in Fig 10 were corrected using equation 2 below and re-plotted in Figure 11 to better represent the estimated volume of oxygen dumped into the chamber atmosphere as a result of purges and leaks.

Equation 2: **VO₂ dumped into the chamber =**
VO₂ used – (VO₂ in supply lines) – (VO₂ in lungs + VO₂ in breathing circuit) – (metabolic VO₂)

Where:

VO₂ used = Total volume of oxygen used by each subject at time point (t) derived from changes in individual bottle pressures (i.e. Volume data presented in Fig. 10).

VO₂ in supply lines = Total volume of oxygen remaining in the high pressure O₂ supply lines from the supply cylinders to the MBS 2000 demand regulator at time point t for all subjects. = (Pressure in supply line at time t * floodable volume of supply lines [i.e. 0.06923 liters])/ 14.7

VO₂ in lungs = $0.8 * (\text{Functional Residual Capacity (FRC)} + \text{tidal volume (TV)}) * \text{BTPS to STPD correction factor [i.e. 0.931]}$. The fractional concentration of O₂ in the lungs was assumed to be 0.8 and the TV was assumed to be 1 liter. FRC was estimated from the subject's age (A) and height (H) using equation 3 below (from Stocks and Quanjer 1995):

Equation 3: $\text{FRC} = (2.34 * H) + (0.001 * A) - 1.09$

VO_2 in the breathing circuit = $0.8 * (\text{MBS 2000 dead space [i.e. 1.34 liters]} + \text{volume remaining in breathing bags at the end of a TV inspiration [i.e. assumed 2 liters]}) * \text{BTPS to STPD correction factor}$. The VO_2 in the breathing circuit was assumed to change very little between subjects and was therefore fixed at a constant value of 2.5 liters.

Metabolic $\text{VO}_2 = 0.4 \text{ l/min} * \text{time}$

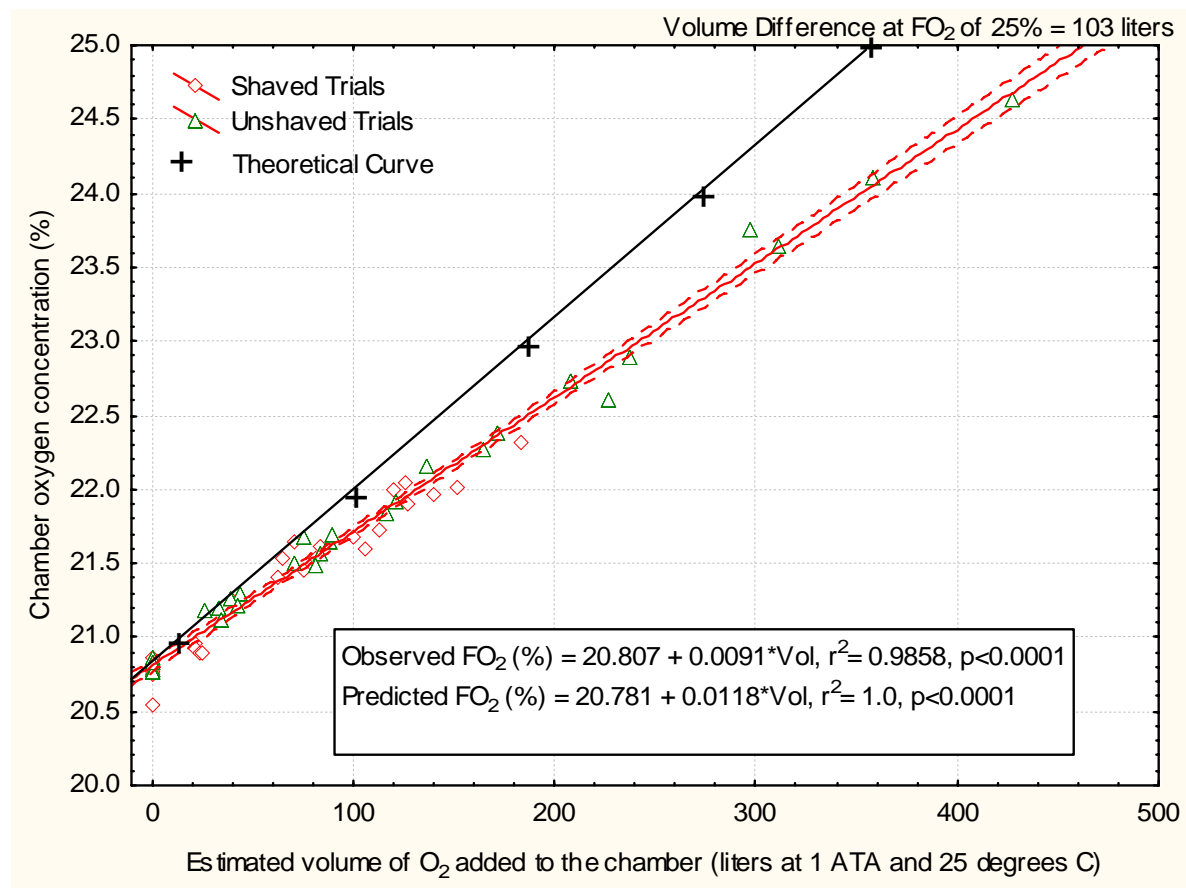


Figure 11: Change in chamber oxygen concentration as a function of the estimated volume of oxygen added to the chamber from purges and leaks during the shaved and unshaved leak trials. The linear regression and its 95 percentile confidence limits that were fit to the observed data are shown together with the theoretical curve. See text for further details.

As can be seen from Fig 11 the applied corrections to the oxygen volume improved the fit of the regression line from an $r^2 = 0.9279$ (see Fig. 10) to 0.9858. The regression line through the observed data now predicts that approximately 460 liters of O_2 would raise the chamber O_2 concentration from 20.8% to 25%. The above corrections to the volume of O_2 used are thus able to account for 61% of the difference between theoretical calculations and the observed curve in Fig 10. However, as shown in Figure 11 the observed volume of O_2 needed to raise the chamber

O₂ concentration from 20.8 to 25% is still approximately 100 liters or 28% greater than that calculated from theory. We therefore consider the possibility that the measured chamber O₂ concentration underestimates the true oxygen fraction in the chamber to help explain the remainder of the difference between the observed and predicted curves in Fig 11.

Part of the underestimation of the chamber O₂ concentration measurements is likely due to the assumptions inherent in the theoretical curve shown in Fig 11. The theoretical curve assumes that when oxygen is added to the chamber there is complete and instantaneous mixing of the gases. In reality this is not true since it will take time for the added oxygen to diffuse and fully mix with the chamber atmosphere. Thus at the instant when oxygen is being added to the chamber, if the sample line is located some distance away from where the O₂ is added, the measured O₂ concentration will not reflect the addition of this oxygen until the bolus of O₂ has had chance to mix with the chamber atmosphere. In the above analysis, measurements of chamber O₂ concentration were made at the exact same time point as the bottle pressure measurements used in calculating individual oxygen usage. Thus if one or more subjects had purged immediately before one of the sample points, the chamber oxygen concentration at that time point would likely underestimate the actual (fully mixed) chamber O₂ concentration.

One other factor that would tend to result in a falsely lower chamber O₂ concentration for a given volume of oxygen added would be any diffusion or leaking of N₂ into the chamber from the external atmosphere. This source of error is likely to be small due to the fact that any leaks if present in the chamber seals or fittings will likely be positive leaks (i.e. leaks of gas out of the chamber) due the small increase in chamber internal pressure resulting from the additional volume of the O₂ added to the chamber atmosphere from the purges.

Using equation 2, individual estimates of the amount of oxygen leaking out of each subjects MBS 2000 unit as a result of purges and other leaks (leakVO₂) was determined at 15 minute intervals for both the shaved and unshaved trials. The mean values and 95% confidence limits for leakVO₂ are shown in the top panels of Figure 12. A three-way split plot ANOVA of the data in the top panels of Fig 12 revealed that the amount of O₂ leaking into the chamber increased significantly over time ($F_{3,48} = 43.90$, $p < 0.0001$) and was on average 65% greater during the unshaven trials compared to the shaven trials ($F_{1,16} = 4.74$, $p < 0.05$). Although there was no overall significant difference for the leakVO₂ between the submariner and diver groups ($F_{1,16} = 2.15$, $p = 0.16$), there was a significant two-way interaction between subject group and facial hair condition (i.e. shaved vs. unshaved). Tukeys Post hoc analysis of this two-way interaction showed that while the diver's leakVO₂ was statistically similar to the submariners for the clean-shaven trials ($p > 0.05$), it was more than double that of the submariners during the unshaved trials ($p < 0.05$). This latter observation reflects the heavier beard growth of the diver group compared to the submariner group.

The change in O₂ leak rate with time is shown in the lower plots of Fig 12. Note that due to the required initial purge and the sporadic nature of the timing of additional purges the oxygen leak rate is not necessarily a constant value. The high initial leak rate at minute 15 predominantly

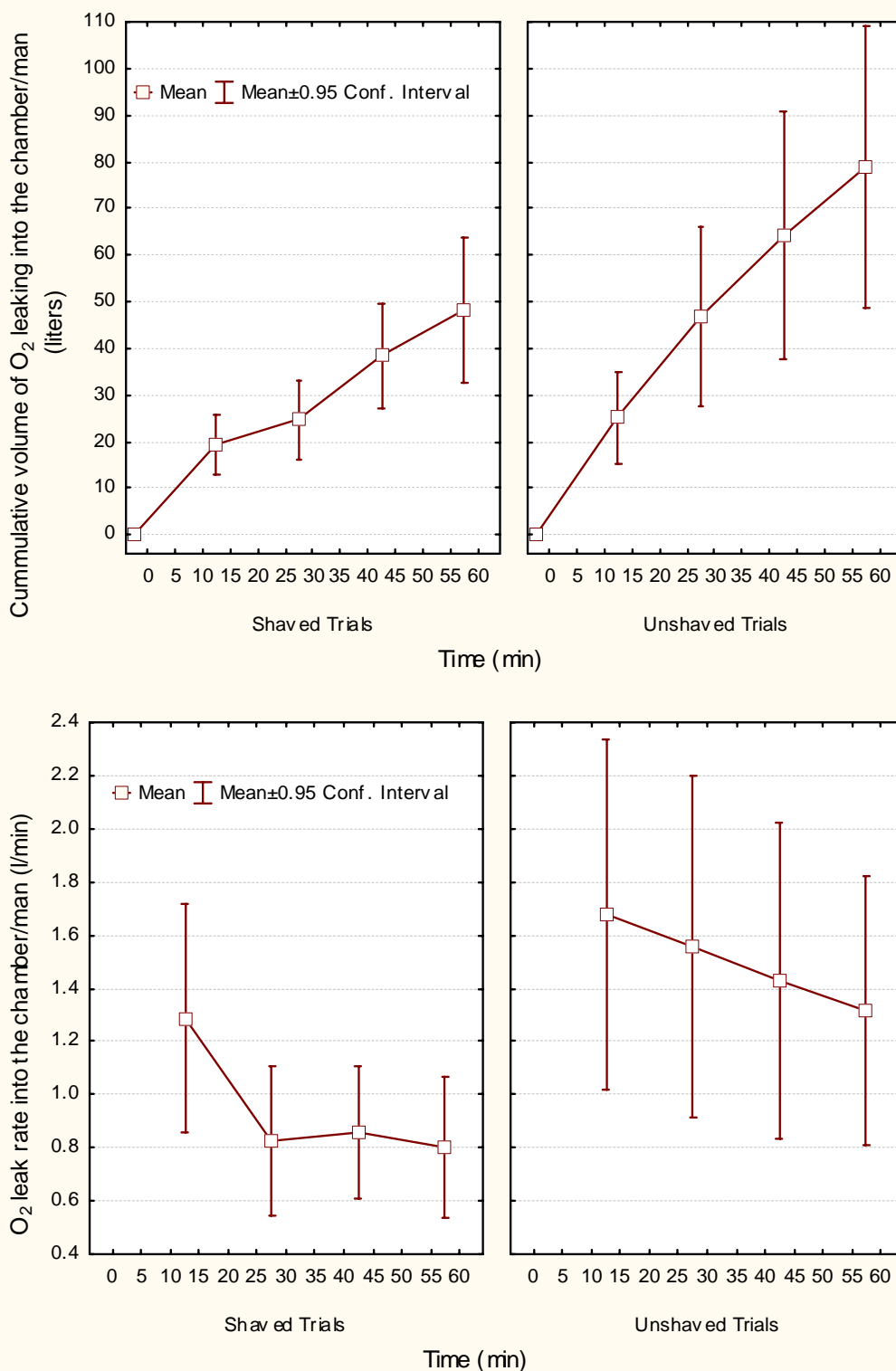


Figure 12: Cumulative volume of O₂ leaking into the chamber/man (top plots) and associated mean O₂ leak rates/man (lower plots) as a result of purges during the shaved and unshaved trials. Data are mean values \pm 95 % confidence intervals (n=18).

reflects the amount of oxygen dumped into the chamber during the initial purge. Oxygen leak rates subsequent to the 15-minute time point reflect the volume of O₂ dumped into the chamber as a result of additional purges performed when the FiO₂ within the rebreather dropped below 0.70. For the shaven trials (Fig 12 lower left plot) it appears that after the initial 15 minutes, leak rates remain constant at approximately 0.8 l/min for the remainder of the trial. In contrast during the unshaven trials there appears to be a trend for a reduction in O₂ leak rates with time. Nevertheless, oxygen leak rates during the unshaven trials were on average 59% greater than during the clean-shaven trials (Mean \pm SD leak rate for shaved trials = 0.94 ± 0.64 l/min/man, unshaved = 1.50 ± 1.19 l/min/man).

Discussion and Recommendations

The mean FiO₂ level during open circuit administration of O₂ via an oral nasal mask will likely be somewhat less than 1.0 due to mask leaks. During the original testing of the US Navy treatment Tables it was assumed that the FiO₂ provided by BIBS was 0.80 (cite from Hennessey and Allain, 2005 from Goodman and Workman, 1965). Using a similar criteria if the mean time taken for the FiO₂ within the MBS 2000 unit to fall to 0.80 can be considered a reasonable compromise between purge frequency and oxygen dosage for a decompression treatment, then based upon the group data for the clean-shaven trials it is recommended that a purge be performed every 10 min during the initial O₂ breathing period. Thus during the first 30 min O₂ breathing period a total of 3 purges (inclusive of the initial purge) would be needed. According to the findings in section I, after the initial purge a single 15 sec CR15 purge should be sufficient to raise the FiO₂ from 0.80 to >0.90. Using the group mean data for the purge volume required for the CR15 purge given in section I (i.e. 28.4 liters at 1 ATA and 25 °C), the total volume of oxygen required per person for a 30 minute oxygen breathing period at standard temperature and pressure will be approximately 57 liters. This value equates to an oxygen usage rate of 1.9 liters/min/subject at standard temperature and pressure.

Based upon the increased oxygen requirements required for the unshaved trials it is recommended that individuals with heavy beard growth shave prior to donning the MBS 2000 mask for a treatment to ensure a good mask seal. Alternatively, replacing the MBS 2000 oral nasal mask with a T-bit mouthpiece and occluding the subject's nose with a nose clip may reduce the amount of air leaking into the rebreather for those subjects with heavy beard growth.

Conclusions

Heavy beard growth increases the amount of chamber air leaking around the sides of the MBS 2000 oral nasal mask into the breathing circuit leading to an increased purge frequency and an increase in the volume of oxygen used to maintain the FiO₂ above a given level. This increased purge frequency can more than double the oxygen requirements needed for a treatment.

During the first 15-minute oxygen period the high rate of oxygen leaking into the chamber atmosphere reflects the volume of oxygen used during the initial purge. After the initial 15 min period the average rate of oxygen leaking into the chamber atmosphere/man in clean-shaven subjects is approximately constant at 0.8 l/min. This leak rate assumes that subsequent purges are performed only when the FiO₂ in the rebreathing circuit drops below 0.70.

III. Reduced Purge Volume Procedures using a Modified MBS 2000 Closed-circuit O₂ Rebreather.

Introduction

Results showing the efficiency of 5 different purge procedures were presented in a preliminary report to NAVSEA on Jan 6th 2005. Based on these preliminary results NAVSEA chose the CR15 purge procedure for the follow on chamber leak test studies. Although the CR15 purge procedure reduced the purge volume by approximately two thirds that required by the currently recommended purge procedure, mission requirements dictated that additional savings in oxygen usage were needed. After a meeting between representatives from NAVSEA, NSMRL, Oceaneering Int. Inc. and Dive Lab Inc. on Feb 15th 2005 it was decided that one way to increase purge efficiency was to modify the MBS 2000 unit (see MBS-2000 UI-05 meeting notes from Mark Vann Emmerick dated 2/15/05). One of the findings from the initial study was that operation of the overpressure toggle valve was problematic due to the small orifice that caused a high back pressure during exhalation when the regulator was depressed during the CR purge procedure. The high backpressure resulted in most of the exhaled breath escaping around the sides of the mask rather than through the expired port of the rig thus preventing effective purging or flushing of the expired side of the rebreathing circuit. A modification to the MBS 2000 that would reduce this backpressure would theoretically improve the effectiveness of the purge procedure and possibly enable the purge volume to be reduced. Two design modifications were considered. First, the overpressure toggle relief valve would be replaced with a pop-off type valve with an increased orifice size to reduce backpressure while purging. The second design modification had the same objective but achieved reduced backpressure during purging by placing a Y-valve on to the expired side of the main body of the MBS 2000. During a purge the Y-valve would be rotated to direct the expired gas and any additional gas flow to the atmosphere. This would allow the subject to purge their lungs as well as the expired side of the rig without having to operate the overpressure relief valve. Once the purge is completed the Y-valve is rotated to direct the exhaled breath to the closed-circuit breathing loop.

Objectives

- I. Compare the effectiveness of a single 15 sec purge procedure with the CR15 purge procedure to determine if reducing the purge volume by approximately one half would significantly impact the starting FiO₂ and the rate of decline in FiO₂ during closed-circuit breathing following an initial purge.
- II. Determine the effectiveness of the two design modifications described above on purge efficiency by measuring the starting FiO₂ and the rate of decline in FiO₂ during closed-circuit breathing following an initial purge.

Methods

Subjects

Subjects were 1 submariner and 7 divers. All subjects had participated in the previous trials assessing the effectiveness of different purge procedures for the MBS 2000. Subjects were briefed on the studies objective and provided informed consent.

Apparatus

MBS 2000 configuration

The new main body assemblies incorporating the new vinyl bags were used. The second stage over bottom pressure for the regulator was set at 70 psi for all tests. During the CR15 purges (Purge C) a toggle overpressure relief valve was placed in the main valve body on the inspired side of the circuit. For purge procedures A and B the toggle overpressure relief valve was replaced with a pop-off valve made by the manufacturer Dive Lab Inc, Panama City, FL. During purge procedure B, a Y-valve was added between the end of the expired breathing hose and the main body, and the pop-off valve was closed shut. A picture of the pop-off valve is shown in Fig 13. Flow through the pop-off valve was through six 9.9 mm² cross sectional area holes giving a total area for flow of 59.6 mm². The Y-valve is shown in Fig 14 and was a commercial off the shelf product (PP Three-Way, Two-Position Elliptic Valve, 3/4" NPT(F) connectors, part number EW-98150-04, Cole Parmer Instrument Company, Vernon Hills, IL). When the Y-valve was positioned to the open circuit configuration the exhaled breath was expelled to the ambient atmosphere through a single orifice with a cross sectional area of 195 mm².



Figure 13: Photograph of the MBS 2000 main valve body showing the pop-off valve. The breathing bags, breathing hoses and CO₂ canister have been removed for clarity.



Figure 14: Photograph of the Y-valve attached to the expired side of the MBS 2000 main valve body. The valve is currently in the open circuit position. The breathing bags, breathing hoses and CO₂ canister have been removed for clarity.

Procedure

Each subject conducted the five purge procedures described below. All subjects completed purge C approximately two months prior to conducting the other purges. Purge procedures A, B, D and E were conducted on the same day with the order randomized among the subjects. After each purge procedure the MBS 2000 unit was flushed with cool fresh air to bring the fractional oxygen content within the breathing loop back to 0.21. The experimental set up was the same as that described in section I above except that the R17-D oxygen cell as well as the S-3A oxygen analyzer was used to continuously monitor the oxygen content in the rebreathing loop. Gas samples were drawn by the S-3A once the purge procedure had been completed and were used to provide a crosscheck on the FiO₂ measured using the R17-D oxygen cell.

Purge A: Pop-off valve configuration with 15 sec free flow purge

After a deep breathe out the subject dons the mask and begins purging by pressing the demand regulator for 15 sec. During the 15 sec purge the subject conducts three deep inspirations and expirations. After 15 sec of purging the pop-off valve is closed and the subject begins rebreathing for 5 min.

Purge B: Y-valve configuration with 15 sec free flow purge

The Y-valve is positioned so that the expired breath is directed to open circuit (i.e. to the atmosphere). The subject dons the mask and fully expires. At the end of the expiration he begins purging by pressing the demand regulator for 15 sec. During the 15 sec purge the subject conducts three deep inspirations and expirations. After 15 sec of purging the Y-valve is rotated to closed-circuit mode and the subject continues rebreathing for 5 min.

Purge C: Toggle overpressure relief valve configuration with two 15 sec free flow purges

Data for this trial was taken from the initial CR15 purge evaluation. The procedure for the CR15 is given in section 1 of this report. Note that the toggle overpressure relief valve was not activated during this purge procedure.

Purge D: Pop-off valve configuration with four VC breaths

After a deep breath out the subject dons the mask and begins purging the MBS 2000 by performing four deep VC inspiration and exhalations while maintaining the breathing bags fully collapsed by squeezing them tightly. During the first three exhalations the expired breath is directed through the pop-off valve. During the fourth inspiration the pop-off valve is manually closed by screwing the cap down onto the rubber valve and the breathing bags are released so that the final (fourth) exhalation is directed into the closed-circuit breathing loop. The subject then continues rebreathing for 5 min.

Purge E: Single fill empty (SFE) purge with Y-valve configuration

For a single fill empty cycle the subject ensures the MBS breathing bags are fully deflated. He then closes the slider/plunger valve on the mouthpiece manifold and fills the breathing bags to full capacity by depressing the regulator purge valve. During this procedure the Y-valve should be in the closed circuit position. The subject then exhales to RV and dons the MBS mask, opens the slider/plunger and takes a big deep breath in. At the same time he turns the Y-valve to the open circuit position. He then exhales through the Y-valve to atmosphere. The subject repeats the above procedure of inspiring from the breathing bags and exhaling to atmosphere until the breathing bags are fully deflated. Once the breathing bags are fully collapsed the subject rotates the Y-valve to the closed-circuit position and begins rebreathing on the unit. This purge procedure is usually completed within four deep breaths.

Data collection and analysis

Prior to each purge procedure the pressure of the oxygen cylinder (M9 size) was recorded. Each test was conducted for 6 minutes with bottle pressure and FiO_2 measured and recorded on line at 50 Hz using the BIOPAC A/D computer system. The volume of oxygen used at the end of each purge procedure (i.e. 30 s after beginning closed circuit breathing) was determined from the change in bottle pressure. For the purpose of analysis the instantaneous inspired fraction of oxygen (FiO_2) was taken at 4 discrete time intervals (30, 60, 120 and 240 sec) following the onset of closed-circuit breathing.

Statistical analysis comparing the FiO_2 among the purge procedures over the four time points was performed using two-way repeated measures ANOVA. Post hoc analysis was conducted using Tukey's HSD test. Statistical significance was set at $p < 0.05$.

Results

The purge procedures using the modified MBS 2000 used a similar amount of oxygen but demonstrated significant differences in purge efficiency. The volume of oxygen used (liters at 1 ATA and 25 °C) for purges A, B and D and E were (mean \pm SD liters), 14.5 ± 0.6 , 14.7 ± 0.9 , 14.3 ± 4.3 and, 12.5 ± 1.5 liters respectively ($p > 0.05$ i.e. NS). The volume of O₂ used for the CR15 (purge C = 28.2 ± 1.7 liters) was significantly greater than all the other purge procedures ($p < 0.05$). Subjects reported significant backpressure during exhalation during Purge A, C and D, but no backpressure when conducting Purge B or E. Back pressure was clearly evident during Purge A and C from the leak noises made as oxygen escaped around the sides of the mask during exhalation.

Results from the repeated measures ANOVA revealed significant main effects for purge procedure ($p < 0.00001$), time interval ($p < 0.00001$) and a significant two-way interaction between purge procedure and time interval ($p < 0.005$) on the post purge FiO₂. The highest mean FiO₂ over the four time points was achieved following Purge C (mean FiO₂ = 0.92) and the lowest was observed following purges A and D (mean FiO₂ = 0.76 for both purges). The FiO₂ following purge A, D and E were lower than that observed following purges B and C at all time points (all post hoc comparisons $p < 0.001$). The mean FiO₂ over the four time points following Purge B was statistically similar to Purge A (mean FiO₂ = 0.88; $p = 0.15$), however, post hoc analysis of the two-way interaction between purge procedure and time interval revealed that the rate of decrease in FiO₂ was greater following Purge B than Purge C (see Fig 15). This was evident by the fact that while Purge B and C raised the FiO₂ at 30 s to the same level (i.e. 0.93), after only an additional 30 s the FiO₂ following purge B had dropped significantly below that recorded at the same time point following Purge C (0.89 vs. 0.93; $p < 0.05$). With increasing time following the purge the difference in FiO₂ between curves B and C became more pronounced (see Fig 15).

Figure 16 compares the FiO₂ responses following purges D and E, which were the only purges that did not manually activate the regulator purge button. The SFE purge with the Y-valve configuration (purge E) attained a significantly higher FiO₂ ($p < 0.05$) across most of the time points than the purges that used the pop-off valve configuration (i.e. purges A and D). However, it is clear that both purge procedures in Fig 16 and purge A in Figure 15 were unable to raise the FiO₂ to > 0.90 . Only purge procedures B and C were able to attain a starting FiO₂ > 0.90 .

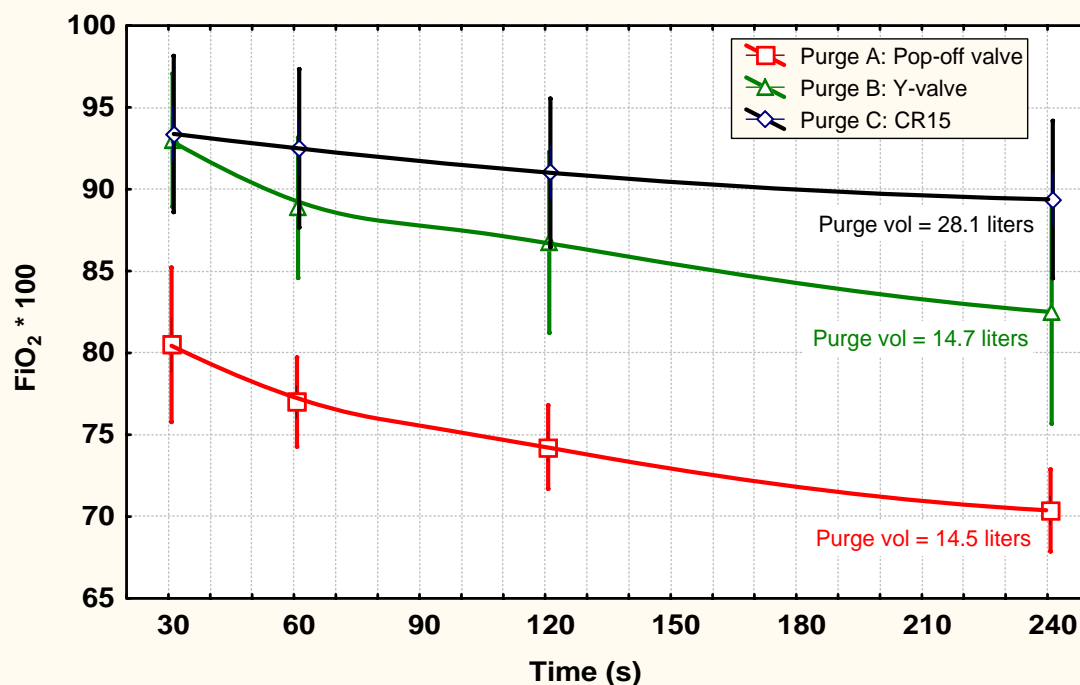


Figure 15: Changes in the inspired oxygen concentration over time following purge procedures A, B and C. Values are means (n=8) and SD (error bars). Data are fitted with a distance weighted least squares. See methods above for a description of purge procedures A, B and C.

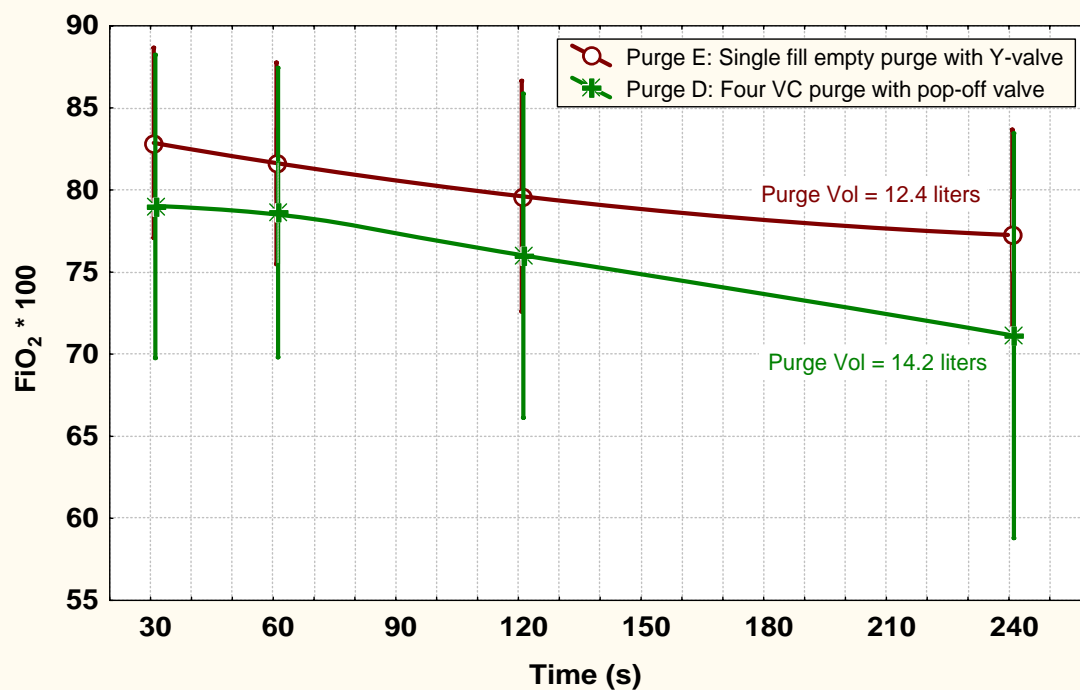


Figure 16: Changes in FiO_2 following a SFE purge with the Y-valve (Purge E) and a four VC purge using the pop-off valve (Purge D). Values are means (n=8) and SD (error bars). Data are fitted with a distance weighted least squares.

Discussion

A comparison of the purge results between the Y-valve modification and the pop-off valve modification (Purge A vs. Purge B and Purge D vs. Purge E) clearly indicate that the Y-valve modification results in a more effective purge than the pop-off valve modification. The low initial FiO_2 achieved following purges A and D was likely due to the high back pressure of the pop-off valve preventing full flushing of the exhalation side of the rig. This conclusion is based on the fact that the same volume of oxygen was used for Purge B as for Purge A but Purge B was able to raise the FiO_2 on average 0.11 above that achieved following Purge A. Furthermore, the effective cross sectional area for flow through the pop-off valve was only 60 mm^2 which would have severely restricted flow compared to the much larger cross section for flow (195 mm^2) for the Y-valve.

A second observation from the data is that, despite a different initial starting FiO_2 for the different MBS 2000 configurations, the decline in FiO_2 with time was similar between the Y-valve and pop-off configurations (i.e. compare the slope of the curves A and B in Fig 15 and the slopes of D and E in Fig 16). The only purge condition that was different was the CR15, which showed a slower rate of decrease in FiO_2 than the other purges. This suggests that the additional volume of oxygen used for the CR15 purge was beneficial in reducing the rate at which nitrogen accumulated in the breathing loop. This latter observation likely reflects the fact that more than 15 liters of oxygen are required to overcome the initial rate of N_2 off-gassing from the lungs. Thus while purge B used half the volume of O_2 to attain the same starting FiO_2 as purge C, gas mixing with any dead space in the breathing loop and additional N_2 off-gassing from the lungs that occurred following purge C likely resulted in the greater rate of decline in the FiO_2 .

Conclusions

- A single 15-second purge using the Y-valve configuration enabled the same starting FiO_2 to be achieved as for the CR15 purge with half the volume of oxygen. However, the additional volume of oxygen used during the second 15 sec purge with the CR15 purge procedure helped reduce the rate of decrease in FiO_2 over the first 4 minutes following the purge.
- A single 15-second purge using the pop-off valve configuration was unable to raise the FiO_2 in the breathing circuit above 0.90.
- With the pop-off valve configuration a four vital capacity purge procedure used a similar amount of oxygen and showed essentially the same FiO_2 vs. time profile as a single 15 sec purge in which the regulator purge button was depressed for 15 sec.
- A single fill empty purge using the Y-valve configuration produced higher FiO_2 values than the 4 VC purge with the pop-off configuration despite using a similar volume of oxygen.
- Based upon the above results it appears that an initial $\text{FiO}_2 > 0.90$ can be achieved with a purge volume of approximately 15 liters in well trained subjects using the Y-valve configuration, but that more than 15 liters of O_2 are required if FiO_2 levels within the breathing loop are to be maintained above 0.80 for longer than 5 minutes.

Recommendations

The cross-sectional area for gas flow in the current pop-off valve was found to be too small and should be increased to at least the same size or greater than that of the Y-valve cross sectional area to avoid significant flow restriction during the purge process. Ideally the cross sectional area for flow through either a pop-off valve or a Y-valve should not be less than the smallest cross sectional area within the breathing loop (i.e. 314 mm²). Since the current pop-off valve does not enhance purging efficiency it is not recommended for inclusion in the next version of the unit unless it is modified to increase gas flow.

The use of a SFE or multiple vital capacity purge (i.e. Purges D and E) do not confer any advantage in either attained FiO₂ or oxygen volume required for the purge over that attained following a 15 sec free flow purge (i.e. Purge A). In view of the relative simplicity of operation for the free flow purge this purge is still the recommended purge procedure.

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continued

current version of the MBS 2000. This was accomplished via three experiments. The first experiment focused on identifying the optimum purge procedure. The second experiment used the optimum purge procedure from Experiment 1 to determine mask leak rates and the build up of O₂ in the chamber in clean-shaven and unshaven subjects. The final experiment evaluated two design modifications to the MBS 2000 and the effectiveness of these modifications for reducing the purge volume. The specific objectives for the three phases are given below.

OBJECTIVES

1. Determine the simplest and most efficient way to purge the MBS 2000.
2. Determine the relationship between the inspired oxygen fraction achieved and the volume of O₂ used for a purge.
3. Assess differences in purge efficiency between divers and submariners.
4. Obtain O₂ consumption and rig leakage data that will allow calculation of the total volume of O₂ needed to support an operation.
5. Determine the average number of purges required to maintain the O₂ level in the breathing loop above 75%, above 80%, above 85% and above 90% during a 60 min breathing period following an initial purge.
6. Determine mask leak rates in shaven and unshaven subjects at 1 ATA.
7. Determine the rate of build up of O₂ in the enclosed atmosphere of the chamber over a 60 min period.
8. Compare the effectiveness of a single 15 sec purge procedure with a 2 x 15 sec purge (CR15 purge procedure) to determine if reducing the purge volume by approximately one half would significantly impact the starting FiO₂ and the rate of decline in FiO₂ during closed-circuit breathing following an initial purge.
9. Determine the effectiveness of two MBS 2000 design modifications (a pop-off valve and a Y-valve) on purge efficiency.

METHODS

All experiments were conducted at 1 ATA. For Experiments 1 and 2 subjects were 9 submariners, age 21.6±6.9 (mean±SD) yrs, 4.8±0.6 L vital capacity (VC) and 9 divers, age 34.0±11.8 yrs, 5.3±0.6 L VC. A subset of these subjects (7 divers and 1 submariner) participated as subjects in Experiment 3. Throughout each experiment the FiO₂ of each unit was monitored using an O₂ cell placed on the inspired side of the rebreathing circuit. The volume of oxygen used by each subject was monitored by measuring changes in bottle pressure. In Experiment 1 each subject conducted five different purge procedures. Purge efficiency for each purge procedure was determined by comparing the volume of O₂ used for the purge with the point sample FiO₂ achieved after 30 s of rebreathing. Differences in purge volume and FiO₂ achieved between the five purge procedures were assessed using a split plot repeated measures ANOVA design.

Experiment 2 was performed with subjects seated at rest in the 307 cubic foot inner lock of NSMRL's treatment chamber. Trials consisted of a single 60-min O₂-breathing period in which subject's purged the MBS-2000 at the start of the test and then again only if their FiO₂ dropped below 0.70. Each subject completed a clean-shaven trial (CT) followed by an unshaven trial (UT) after abstaining from shaving for 7-14 days. The purge procedure used during Experiment 2 involved two 15 sec purges in which the subject depressed the regulator purge button and conducted 3 VC breaths during each 15 sec purge. During each trial the rate of rise of the O₂ concentration in the chamber atmosphere was monitored using a paramagnetic O₂ analyzer. Estimates of the volume of O₂ dumped into the chamber was calculated at 15 min intervals by subtracting metabolic O₂ consumption and the combined O₂ volume remaining in the supply lines, lungs and rebreathing circuit from the total volume of O₂ used. Differences in O₂ usage and O₂ volume dumped into the chamber between trials for different levels of beard growth (light, medium, and heavy) were analyzed using repeated measures ANOVA.

The procedure for Experiment 3 was the same as that for Experiment 1. Each subject performed four different reduced-volume purge procedures using modified MBS 2000 rigs. The reduced volume purge procedures were designed to use approximately half the volume of O₂ than that used for the CR15. Two of the purge procedures used the MBS 2000 fitted with a newly designed pop-off valve. In the other two purges a Y-valve was incorporated in the exhaled breathing line to assist with purging. The efficiency of the reduced volume purges with the modified MBS 2000 was compared with the CR15 purge and the unmodified MBS 2000 using repeated measures ANOVA.

continued

RESULTS

Results of Experiment 1 showed that the best compromise between purge volume, starting FiO_2 and simplicity of operation was the CR15 purge. This purge procedure involves two 15 sec purges in which the subject performs 3 VC breaths during each 15 sec while depressing the regulator purge button. Thirty seconds of rebreathing separated the two 15 sec purges to allow for gas mixing in the lungs and rebreathing circuit. The CR15 was able to raise the mean FiO_2 above 0.90 using two thirds less volume than that used by the currently recommended (CR) purge procedure (i.e. 28 vs. 81 liters). Over the five different purge procedures, divers used significantly more O_2 than the submariners but achieved an FiO_2 level that was on average 0.09 above the submariners. Using data from single vital capacity purges, the relationship between the FiO_2 achieved and the VO_2 used was found to be an exponential function that predicted at least 6 VC were required to raise the FiO_2 within the breathing circuit from 0.21 to >0.90 .

Results from Experiment 2 showed a significant two-way interaction between beard growth category and the difference in the number of purges between CT and UT ($p<0.05$). Post hoc analysis revealed that subjects with light and medium beard growth showed no change in the number of purges between the CT and UT, whereas subjects with heavy beard growth significantly increased the number of purges during the UT ($p<0.05$). Oxygen usage during UT for these latter subjects was more than double that during their CT ($p<0.05$). The amount of O_2 leaking into the chamber increased significantly over time ($p<0.0001$) and was greater during the unshaven trials compared to the shaven trials (Mean \pm SD leak rate for shaved trials = 0.94 ± 0.64 l/min/man, unshaved = 1.50 ± 1.19 l/min/man, $p<0.05$). For CT it appears that after the initial high leak rate at 15 minutes, leak rates remain constant at approximately 0.8 l/min for the remainder of the trial. In contrast, oxygen leak rates appear to fall over time during UT.

Results of Experiment 3 showed that the reduced volume purge procedures using the pop-off valve configuration were unable to raise the initial FiO_2 to >0.90 . In contrast a single 15 sec purge performed using the Y-valve modification achieved the same starting FiO_2 as for the unmodified MBS 2000 using the CR15 purge (i.e. both $\text{FiO}_2 = 0.93$), but with half the volume. However, post hoc analysis of the significant two-way interaction between purge procedure and time interval ($p<0.005$) revealed that the rate of decrease in FiO_2 was greater following the single 15 sec purge with the Y-valve modification than that following the CR15 purge.

CONCLUSIONS

- Divers use more O_2 than submariners during the purge procedures but attain a higher FiO_2 than the submariners.
- The simplest and most preferred purge procedure is the CR15.
- The CR and CR15 purge procedures were the only procedures tested that achieved a starting $\text{FiO}_2 > 0.90$.
- The CR and CR15 purge procedures achieve a similar FiO_2 , but the CR15 purge achieves this using approximately two thirds less O_2 than the CR purge.
- A mathematical model of the change in FiO_2 following each VC purge predicts that at least 6 VC purges are required to raise the FiO_2 in the MBS 2000 from 0.21 to > 0.90 . Heavy beard growth increases the amount of chamber air leaking around the sides of the MBS 2000 oral nasal mask into the breathing circuit, leading to an increased purge frequency and an increase in the volume of O_2 used to maintain the FiO_2 above a given level. This increased purge frequency can more than double the O_2 requirements needed for a treatment.
- During the first 15-minute O_2 period the high rate of O_2 leaking into the chamber atmosphere reflects the volume of O_2 used during the initial purge. After the initial 15-min period the average rate of O_2 leaking into the chamber atmosphere/man in clean-shaven subjects is approximately constant at 0.8 l/min. This leak rate assumes that subsequent purges are performed only when the FiO_2 in the rebreathing circuit drops below 0.70.
- A single 15-second purge using the pop-off valve configuration was unable to raise the FiO_2 in the breathing circuit above 0.90.
- An initial $\text{FiO}_2 > 0.90$ can be achieved with a purge volume of approximately 15 liters in well trained subjects using the Y-valve configuration, but that more than 15 liters of O_2 are required if FiO_2 levels within the MBS 2000 breathing loop are to be maintained above 0.80 for longer than 5 minutes.